PETITION FOR WRIT OF CERTIORARI

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IN THE

Supreme Court of the United States

CLASSEN IMMUNOTHERAPIES, INC., PETITIONER

v.

BIOGEN IDEC, GLAXOSMITHKLINE, AND MERCK & CO., INC.

PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

PETITION FOR A WRIT OF CERTIORARI

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QUESTIONS PRESENTED

The CAFC has recently made a decision that set precedent on patentability under 35 U.S.C. §101. In *Bilski* the CAFC created a litmus test for patentability under 35 U.S.C. §101, the "machine or transformation" test for business method patents. The application to medical activities, pharmaceutical methods of use, and research tools, in particular diagnostic methods is unclear.

This case, *Classen Immunotherapies versus Biogen Idec et al.*, raises questions concerning the application of this important doctrine:

Is the CAFC's test for patentability under 35 U.S.C. §101, as defined in *Bilski*, the "machine or transformation test" appropriate for determining patentability of a method of using pharmaceuticals and "medical activities"? Do pharmaceuticals including vaccines fall under the definition of an apparatus? Does medical treatment including immunization constitute transformation. Are methods of diagnosing disease or assays for detecting drug adverse events patentable under *Bilski* and if not is *Bilski* too narrow or should it not apply to medical activities?(If the court accepts cert in *Bilski*, this petition for cert should be stayed pending the outcome of *Bilski*).

RULE 29.6

Classen Immunotherapies is a privately owned supchapter S corporation formed in the State of Maryland.

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The opinion of the United States Court of Appeals for the Federal Circuit (Exhibit A) is unreported. The memorandum opinions of the district court (Exhibit B) is unreported.

JURISDICTION

The judgment of the court of appeals was entered on December 19, 2008. The order denying a complete decision was entered on January 13, 2009. A petition for rehearing was timely filed on January 13, 2009 and was denied on February 9, 2009. The mandate from the CAFC was entered February 17, 2009. This Court's jurisdiction is invoked under 28 U.S.C. § 1254(1).

RELEVANT PROVISIONS INVOLVED

35 U.S.C. §101

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

35 U.S.C. §271(e)(1)

> It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention (other than a new animal drug or

veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Act of March 4, 1913) which is primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques) solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.

STATEMENT

This is a case about patentability of methods of using pharmaceuticals and medical activities under 35 U.S.C. §101. The CAFC has made a decision that set precedent for patentability under 35 U.S.C. §101.

The *Bilski* decision defined patentability under 35 U.S.C. §101 but the case involved a specific business method patent. *Bilski* criteria for patentability, the "transformation or machine" test, was applied in the current case to patents covering medical activities (immunization), methods of using specific vaccines (hepatitis B vaccine among others), and research tools (methods of testing vaccines to determine if they cause severe adverse events). The problem with applying the *Bilski* criteria beyond business methods is that *Bilski* did not provide a clear definition of what constitutes an apparatus and what constitutes transformation of an article. For example is an vaccine an apparatus. Is immunization a transformation step? According to the CAFC's decision they are not. However by denying patentability of the patents in the present case the

CAFC's decision is in direct opposition to the clear intent of Congress. Congress has passed special legislation making it clear that Congress intends for "medical activities" (see USC 35 Section 287(c)) to be patentable as well as methods of using pharmaceuticals (Waxman Hatch legislation 21 USC 355(b)(1)). The *Bilski* decision never considered these special legislations which shed light on what Congress intended patentable.

The definitions used in *Bilski* must be sufficiently broad to include these activities. In other words, medical treatment must be considered a "transforming" activity and a pharmaceutical product or device must be considered an apparatus in order for *Bilski* to be applied to pharmaceutical/medical inventions. The CAFC's decision was based solely on the *Bilski* decision. If the *Bilski* petition for cert is accepted, a final decision in this matter, Classen, should be stayed pending disposition of *Bilski*. If *Bilski* is reversed by the US Supreme Court this case *(Classen Immunotherapies versus Biogen Idec et al)* should be sent back to the CAFC on remand.

A. Factual Background

Dr. Classen discovered that common vaccines are causing an epidemic of diabetes and other autoimmune diseases. His discoveries include the finding that immunization schedules starting in the first month of life cause less diabetes than schedules starting later in life. The patents at issue cover safer methods of administering specific vaccines including the hepatitis B vaccine. One patent also covers methods of testing different immunization schedules to

determine a safe schedule.

This civil action for patent infringement was brought by Plaintiff-Appellant, Classen Immunotherapies, Inc., the owner by assignment from Dr. John Barthelow Classen, of United States Letters Patent Numbers: 6,420,139; 6,638,739 and 5,723,283. The Defendants are: Biogen Idec, Inc., Glaxo Smithkline, Inc., Chiron Corporation and Merck & Co., Inc. Each of the patents at issue are based upon the research of Dr. John Barthelow Classen, M.D. Each patent claims priority to the Classen patent application Serial Number 104,529 filed on August 12, 1993.

Dr. Classen's research lead him to invent, a novel "Method and Composition for an Early Vaccine to Protect Against Both Common Infectious Diseases and Chronic Immune Mediated Disorders or Their Sequelae." Dr. Classen's efforts were then, and continue to be directed toward awareness that vaccines cause diabetes and autoimmune diseases. Dr. Classen developed techniques for reducing risks associated with different immunization schedules and patented these techniques in the form of therapeutic methods of use claims in the patents in suit, in particular covering improved, safer methods of using vaccines.

Dr. Classen widely disseminated the findings and conclusions of his research, hoping to bring greater awareness to the need for long term studies of the effects of immunization. Dr. Classen published numerous articles, letters and papers which explain and document the discoveries which lead to his invention. The papers include: "The Timing of Pediatric Immunization and the Risk of Insulin-Dependent

Diabetes Mellitus" co-authored with David Classen, MD and published in Infectious Diseases Clinical Practice in 1997 [1](A330-335); and "The timing of Immunization Affects the Development of Diabetes in Rodents" published in Autoimmunity in 1996. (A336-A344)

Dr. Classen's research was aired by ABC on World News Tonight, (A226-A227) and fueled a debate in the medical community which has included Defendants, as well as The National Immunization Program of the Centers for Disease Control and Prevention, The National Institutes of Allergy and Infectious Diseases and The Vaccine Education Center of The Children's Hospital of Philadelphia, as well as many physicians and clinical researchers. (eg. A217-A219 and A220-A225 and A228-A245 among others) The Defendants have sponsored and conducted many studies and evaluations to test Dr. Classen's work and to evaluate the risks and benefits associated with vaccine schedules. (A392-A397) Defendants have also sponsored meetings and publications to disseminate these findings. (A385-A465 and A469-A474)

Patentable inventions often come from research. However, there is a difference between the scientific results of the research and the patentable uses of those scientific results. Dr. Classen discovered a potential relationship between vaccination and autoimmune diseases. Dr. Classen patented practical methodologies for reducing risk and or increasing benefit from this discovery.

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[1] Citations refer to Appendix from the appeal filed with the CAFC

The patents in suit do not claim the natural phenomenon of a reaction between a vaccine and a human autoimmune system. The patents do not claim the basic scientific knowledge gained through the research of Dr. Classen. The scientific discoveries of Dr. Classen are found in his literature and publications for the medical community to read, review, test and comment upon.

The patents claim methods for utilizing the knowledge of this phenomenon to reduce risk or increase benefit of immunization through selection of favorable immunization schedules. Furthermore vaccines are not products of nature but are products of man. Use of these agents either therapeutic use or experimental use are not covered by the "law of Nature" as stated by the US Supreme Court in *Diamond vs Chakrabarty,* (447 U.S. 303 (1980).

B. Earlier Proceedings

Procedural History

Classen evaluated the screening of vaccine schedules conducted by the defendants (step I) and the published literature and recommendations for vaccination schedules (step II) disseminated by the defendants.

Based upon these evaluations Classen filed suit for infringement, contributory infringement and inducement to infringe in August, 2004.

On November 19, 2004, GSK and Biogen filed motions to dismiss based upon the safe harbor

protection of 35 U.S.C. §271(e)1. The motions argued that the Court of Appeals for the Federal Circuit decision in Integra Lifesciences I, Ltd. v. Merck KGaA, 2003 U.S. App. LEXIS 27796, 9-11 (Fed. Cir., 2003) supported their motion to dismiss. Classen argued in opposition that the decision did not support the motion to dismiss. Briefing was closed on January 2005. On June 13, 2005, the Supreme Court issued its ruling in *Merck v. Integra*, (2005), partially reversing and remanding the decision of the Federal Circuit.

In its Order dated July 22, 2005, (A47-A60) the District Court ruled, without hearing, that the activities of Defendants GSK and Biogen were entitled to the "safe harbor" protections of 35 U.S.C. §271(e)1.

Finally, in an Order dated August 16, 2006 (A24-A37) the District Court, without oral hearing, denied a Motion for reconsideration filed by Plaintiff on Merck's non-infringement, and granted Summary Judgment of invalidity, finding the patents invalid under 35 U.S.C. §101 for patenting a law of nature.

On September 7, 2006 Appellant, Classen, appealed from three rulings of the District Court for the District of Maryland. One of those rulings was an Order dated August 16, 2006 wherein the District Court granted summary judgment of invalidity, finding the patents invalid under 35 U.S.C. §101 for patenting an abstract idea. Classen also appealed the December 15, 2005 order of unenforceability under 35 U.S.C. § 271(e)1. The appeal was heard at the Federal Circuit in July 2007, under the "laws of nature, natural phenomena and abstract ideas" test. The oral argument

was held two months prior to the initial hearing of *In Re Bilski*, 545 F.3d 943 (Fed. Cir. 2008)(en banc).

Oral arguments were made before the Federal Circuit in July 2007. The Federal circuit rendered a decision on the case December 19, 2008. The complete decision read:

> *"In light of our decision in In re Bilski, 545 F.3d 943 (Fed. Cir. 2008) (en banc), we affirm the district court's grant of summary judgment that these claims are invalid under 35 U.S.C. § 101. Dr. Classen's claims are neither "tied to a particular machine or apparatus" nor do they "transform a particular article into a differeni state or thing." Bilski, 545 F.3d at 954. Therefore we affirm."*

The CAFC never considered the district court's ruling under 271(e)1.

A motion was placed requesting a complete decision on the 35 U.S.C. §271(e)1 issue on December 24, 2008 and the motion was denied on January 13, 2009. An petition for rehearing en banc was requested January 13, 2009 and was denied on February 9.

C. The District Court's 35 U.S.C. §101 Ruling

The District Court in invalidating the patents in suits made two errors in law. The District court's decision to invalidate the patents based on a reason of "law of nature" was in error because it went against the Supreme Court's decision in *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980) In *Chakrabarty*, the Supreme

Court declared "laws of nature" rejection can not be applied to man made inventions. The District court further erred in failing to independently consider the dependant claims but instead rejected the patents based solely on a single main claim making a broad sweeping characterization of the patents without considering the additional limitations of the dependant claims.

Merck filed for Summary Judgment of invalidity alleging that the Classen patents are "merely the mental process of thinking about whether a vaccine schedule has been shown to reduce the risk." The District Court in its Order dated August 16, 2006 found that the '283 patent : "describes only a general inquiry of whether the proposed correlation between an immunization schedule and the incidence of chronic disorders exists. As such, the process is indistinguishable from the idea itself. Accordingly, the '283 patent seeks to patent an unpatentable phenomenon." The District Court also found that the '139 and'739 patents: "are an indirect attempt to patent the idea that there is a relationship between vaccine schedules and chronic immune mediated disorders, the Court finds they are an attempt to patent an unpatentable natural phenomenon".

The patents at issue are not invalid for containing a "mental step", the patents are collectively about (i) comparing two or more vaccination schedules, (ii) determining if one of the schedules has a lower associated risk and (iii) immunizing according to a lower risk schedule.

The patents at issue do not claim a "scientific

truth" that vaccines can have an effect on immune mediated disorders, the patent claims recite methods which can be practiced to "reduce the incidence" of such disorders: Thus, "[w]hile a scientific truth, or the mathematical expression of it, is not a patentable invention, a novel and useful structure created with the aid of knowledge of scientific truth may be." *Diehr*, 450 U.S. at 188, 209 USPQ at 8-9 (quoting Mackay, 306 U.S. at 94); see also *Corning v. Burden*, 56 U.S. (15 How.) 252, 268, 14 L.Ed. 683 (1854)("It is for the discovery or invention of some practical method or means of producing a beneficial result or effect, that a patent is granted . . .") (From the Guidelines for Examination of Patent Applications for Patent Subject Matter Eligibility (A260-A281).

The Supreme Court interpreted the statutory four classes identified in 35 U.S.C. §101 very expansively to "include anything under the sun that is made by man" *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980). The court ruled that man made bacteria are patentable because they don't occur in nature. This ruling has set the standard in determining what is covered by a "law of nature" . The litmus test is whether a product is found in nature. Vaccines are man made and thus methods of screening immunization schedules would not be covered by a law of nature.

The claims of the patent in suit relate to routine "therapeutic methods of use" in particular safer methods of administering vaccines. Such improved methods of use derived from scientific discoveries are patentable:

"[A]n application of a law of nature or

> mathematical formula to a ... process may well be deserving of patent protection." *Diehr*, 450 U.S. at 187, 209 USPQ at 8 (emphasis added); see also *Corning*, 56 U.S. (15 How.) at 268, 14 L.Ed. 683 ("It is for the discovery or invention of some practical method or means of producing a beneficial result or effect, that a patent is granted . . ."))(From the Guidelines for Examination of Patent Applications for Patent Subject Matter Eligibility) (A260-281)

The method of the invention at issue when evaluated as a whole results in a tangible result: the selection of a lower risk schedule and the resultant vaccination of children in accord with that schedule. The claims do not pertain to "thinking about" a schedule. Instead the patents pertain to choosing.

In fact, the District Court found that the claims do not directly patent a law of nature but instead attempt to "indirectly" patent a law of nature. "As it would appear that the 139 and 739 patents are an indirect attempt to patent the idea that there is a relationship between vaccine schedules and chronic immune mediated disorders". (A36) The "indirect" attempt the judge refers to is the utilization of a discovery which is patentable subject matter.

In *LabCorp v. Metabolite*, the inventors discovered that elevated levels of an amino acid called homocysteine are indicative of deficiencies in two vitamins, namely B12 and folate. Such deficiencies are associated with neuropsychiatric disorders, vascular disease and other medical problems. The patent covers the diagnostic method of assaying for elevated levels of

homocysteine and correlating the results with deficiencies of the vitamins. A question in the case is whether doctors could infringe on the patent merely by looking at a test result for homocysteine and then thinking about vitamin deficiency. The lower courts said *LabCorp* had not directly infringed on the patent but rather had induced doctors to do so by performing the correlation.

The Classen patents are more removed from patenting nature than patenting DNA sequences, found in nature. DNA sequences are patented, as well as manufacturing products from DNA sequences. *Schering Corp. v. Amgen* Inc., 18 F.Supp. 2d 372 (D.Del. 1998.) The decision upholding a patent for isolated DNA sequences and recombinant DNA methods for producing interferon protein, but noting that proteins having the same action are natural phenomena.

The District Court erred in fact and law in not crediting the role of dependent claims. A main claim may be invalid but the patent is still valid if there are dependent claims that are valid. The Court in fact made no ruling on any of the dependent claims and acted if they did not exist. The court stated: "the 139 and 739 patents do not describe a particular vaccine or vaccine schedule". Patent '139 has numerous dependent claims (claims 2-29, 33-54, 56-62, 66,69,70) (A165-A167) as does patent '739 (claims 2-70,112-113) (A206-A209), many of which recite specific immunization schedules. For example the dependent claims of '139 described an immunization schedule where the hepatitis B vaccine is given before 42 days (see '139 claim 6, 26, and 28) (A165-A167). The '739 patent claims a schedule where

the hepatitis B vaccine is given prior to 42 days after birth (see '739 claim 51)(A207) Even if the main claim is invalid the dependent claims can be valid. The court made a similar error regarding the'283 patent as described above.

D. 35 U.S.C. § 271(e)1

Neither the District Court nor the CAFC considered 35 U.S.C. § 271(e)1, in light of *Proveris* Scientific...which was decided during the pendency of Classen on appeal. *Proveris* requires that the 271(e)1 issue be reversed.

E. The Federal Circuit's Panel Decision

The Federal Circuit's decision in its entirety reads:

> *"In light of our decision in In re Bilski, 545 F.3d 943 (Fed. Cir. 2008) (en banc), we affirm the district court's grant of summary judgment that these claims are invalid under 35 U.S.C. § 101. Dr. Classen's claims are neither "tied to a particular machine or apparatus" nor do they "transform a particular article into a different state or thing." Bilski, 545 F.3d at 954. Therefore we affirm."*

The Federal Circuit did not rule on the issue of 35 U.S.C. §271(e)1. A motion was made to request a complete decision but this was denied. The Circuit Court left unchanged the District Court's ruling that provided the defendants safe harbor under 35 U.S.C. §271(e)1.

Bilski was argued to a three judge panel on October 1, 2007, was reheard en banc on May 8, 2008 and was decided on October 30, 2008, establishing the "machine or transformation of matter" test for patentable subject matter under 35 USC §101.

Bilski related to a business method patent. Extrapolation to medical activities and methods of using pharmaceuticals is flawed because *Bilski* never considered special legislation passed by Congress clearly signaling its intent to allow patents on medical activities and methods of using pharmaceuticals. The Circuit court erred in invalidating the Classen patents pertaining to medical activities (immunization) and methods of using vaccines. The error was the result of narrowly defining the definitions of "transformation" to exclude medical activities including treatment and "apparatus" to exclude pharmaceutical products. When the definitions are given proper breath then *Bilski* properly applied would uphold the validity, of the Classen patents.

The Circuit Court issued a decision in this matter on December 19, 2008, eighteen months after oral argument and two months after the en banc decision in *Bilski*.

Although the Federal Circuit decision stated that the decision of the District Court was affirmed in light of *Bilski*, neither the District Court nor the parties ever addressed the *Bilski* "machine or transformation of matter" test. Further, the Circuit Court's decision neither explained the reasoning nor the application of the *Bilski* "machine or transformation of matter" test to the facts of the case.

As recognized by the patent community (see: Hal Wegner's Top Ten for 2008, see also: J. Matthew Buchanan, *After Bilski*) the *Classen* appeal was seen as an important opportunity for the Court to address the application of current trend in the application of 35 USC §101. See also: *Patent Docs*, Kevin E. Noonan, *Classen Immunotherapies, Inc. v. Biogen Idec (Fed. Cir. 2008);*

> "The result is also anomalous because the Classen case was widely viewed as foreshadowing how the Federal Circuit will address the issues raised by *Laboratory Corp. v. Metabolite Labs., Inc.* (*LabCorp*), and Justice Breyer's criticism of the scope of that claim under a patentability analysis."

The Federal Circuit, in failing to explain its reasoning behind the brief statement of affirmation has left the patent community to wonder what may be patentable and why. See: Holman's Biotech IP Blog, Friday, December 19, 2008, *Classen v. Biogen: The Federal Circuit Applies Bilski to the Life Sciences*:

> The opinion ducks important issues. Contrary to the holding, the claims do in fact involve a transformation, e.g., claim 1 of 5,723,283 recites a 'method . . . which comprises immunizing mammals in the treatment group of mammals with one or more doses of one or more immunogens . . . .' The immunization of a mammal clearly effects a transformation of a particular article [a mammal] into a different state [a state of induced immunity].

> It is inconceivable that this does not constitute a transformation; if that were the case, it would logically follow that all method of treatment claims are patent-ineligible.

Also: *No Cartesians Here*, from The Fire of Genius:

> What's intriguing about Classen is that it doesn't appear to rely on the more general considerations stated in Bilski, i.e., the need for "meaningful limits on the claim's scope" and the derogation of "insignificant extrasolution activity." Of course, Classen is highly compressed, clocking in at a total of 68 words (including words in citations), so I may wrong about this. But here's the (one and only) sentence providing the court's rationale:
>
> > Dr. Classen's claims are neither "tied to a particular machine or apparatus" nor do they "transform[ ] a particular article into a different state or thing." (Quoting Bilski.)
>
> At first blush, however, Classen Claim 1 *does* appear to recite a transformation of a physical article...

All of the discussions in the patent community agree that immunization is a transformation of matter, thus the *Classen* decision brings into question entire classes of pharmaceutical patents which rely on the step of "immunization" as a "transformation of matter."

> Indeed, listening to the Classen oral argument clearly shows that Judge Moore was intensely interested in the patentability of mental processes at the time. She initiated a discussion on the issue by asking counsel for the patentee to ignore the nonmental immunizing step of the claim at issue ("yes, clearly you're absolutely right...these are not exclusively mental process claims."). (J. Matthew Buchanan, *After Bilski*)

It is important to the establishment of a consistent and predictable body of case law that the Federal Circuit rehear this matter en banc. The patent community deserves an decision which explains the Court's reasoning in finding an immunization patent to be non-statutory subject matter, without the need for speculation.

> Uncertainty is the enemy of innovation. These new uncertainties not only diminish the incentives available to new enterprise, but disrupt the settled expectations of those who relied on the law as it existed. NEWMAN, Circuit Judge, In re Bilski

Claim one of each of the Classen patents includes a step of immunization: Patents '139 and '739: "(II) **immunizing said subject** according to a subject immunization schedule...."

Patent '283: "which comprises **immunizing mammals** in the treatment group of mammals with one or more doses of one or more immunogens...." This step is a transformation of matter. An immunogen is introduced

into the organism. The immunogen transforms the organism to a state of induced immunity.

In addition to the inclusion of the immunization step which transforms matter, the claims recognize the transformation and include further steps of analysis of the relative transformations of matter based upon the immunization schedule implemented:

Patents '139 and '739: "(1) screening .... immunized with one or more doses of one or more infectious disease-causing organism-associated immunogens ... comparing ... inducing a chronic immune-mediated disorder..."

Patent '283: "comparing the incidence, prevalence, frequency or severity of said chronic immune-mediated disorder or the level of a marker of such a disorder, in the treatment group, with that in the control group."

"Inducing a chronic immune-mediated disorder" is clearly also a transformation of matter. The decision of the CAFC in *Classen*, in ruling that immunization, and therefore any treatment of the human body, is not a "transformation of matter," is far reaching. If immunization in Classen's patents is not patentable subject matter under the *Bilski* test, then all immunization patents fail to teach patentable subject matter.

The exclusion of treatment method patents from patentable subject matter is not consistent with Congressional intent to allow patenting of new pharmaceutical uses and patenting of medical activities USC 35 Section 287(c)(2)(a)(ii).

Congress intent regarding patenting medical procedures and methods of using pharmaceuticals was not discussed in the *Bilski* decision but has a clear legislative history. The Hatch Waxman legislation 21 U.S.C. §355(b)(1), states

"The applicant shall file with the application the patent number and the expiration date of any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug" thus further indicating Congress' intent that methods of using pharmaceuticals are patentable. 21 U.S.C. §355 and 35 U.S.C. §287 clearly evidence Congress's intention for *"medical activity" ("the performance of a medical or surgical procedure on a body")* to be patentable. Immunization is an medical activity. The courts reasoning for invalidating Classen's patents under Bilski is in conflict with the clear intent of Congress.

Patents covering method of using pharmaceuticals are an essential part of the intellectual property relating to specific pharmaceutical products. For example a review of the Orange Book listing and the internet for biologics shows that of the top 25 selling pharmaceuticals in 2007, all are protected in the US in part by method of use patents. When looking at patents that use a claim containing immunize, immunization, or immunizing there are at least 1,349 US patents claiming "immunizing." Appellee GSK was issued patents covering immunization that use the phraseology "inducing protective antibodies." Merck and Biogen, have patents which recite immunization or similar process. Thus these methods of immunizations could all be challenged under Bilski if "immunization"

does not induce "transformation of a particular article into a different state or thing". Immunization creates a lasting change by transforming the recipient into a protected state that can last for 20 years or more.

Classen's patents ('283, '139, '739) covers a method of using an pharmaceutical (immunogen) for prophylactic treatment (immunization). A representative claim is claim 1 of the 5,723,283 patent which requires an immunization step. Claim 8 requires that the immunization prevents at least two infectious diseases, clearly a transformation. Claim 20 ties the invention to specific immunogens (i.e. apparatus for preventing infection). 6,420,139 claim 30 is slightly more advanced because it requires immunization of two groups and, after analysis, immunizing an individual according the safer schedule. Claim 31 ties the invention to an hepatitis B immunogen (i.e. apparatus for preventing infection).

Bilski set the test for patentable subject matter as "tied to a particular machine or apparatus" and/or "method step which includes a transformation of matter." Although this test was not briefed nor argued because the *Bilski* decision was issued more than a year after oral argument, the claims of the Classen patents clearly fall within the test for patentable subject matter, because "immunization" which is recited in all of the claims at issue is a "transformation of matter." The panel should rehear this matter in light of the decision in *Bilski*, allowing the parties to brief and argue patentablility under 35 U.S.C. §101 in light of the tests set forth in *Bilski*.

F. The Opinions Dissenting from and Concurring in the Denial of Rehearing En Banc

There were no opinions in the denial of rehearing.

REASONS FOR GRANTING THE PETITION

There are several reasons for granting this petition. The CAFC has made two decisions that set precedent. The *Bilski* decision set precedent regarding patentability under 35 U.S.C. §101. For a business method the current case extended the decision to medical activities, methods of using pharmaceuticals, and diagnostic testing without any discussion or explanation.

The CAFC errored in applying *Bilski* to the present case because Bilski never considered the intent of Congress to allow broad patenting of inventions in these medical areas. If the Supreme Court has already struck down the Bilski decision then the court should send this case back to the CAFC since the criteria for patentability set up by *Bilski* was the sole reason for the ruling of invalidity in this case.

I. This Court Should Review The Federal Circuit's Application in this Case of the *Bilski* Decision Which Sets Precedent for Patentability under 35 U.S.C. §101

The *Bilski* decision failed to consider medical activities and methods of using pharmaceuticals or the special legislation indicating Congressional intent to allow patents on this subject matter. The application of the *Bilski* criteria in Classen indicates it excludes

patentable subject material. The Federal Circuit's exclusion of treatment method patents from patentable subject matter is not consistent with Congressional intent to allow patenting of new pharmaceutical uses and patenting of medical activities USC 35 Section 287(c)(2)(a)(ii). Congress intent regarding patenting medical procedures and methods of using pharmaceuticals was not discussed in the Bilski decision but has a clear legislative history.

21 U.S.C.§355 and 35 U.S.C. §287 clearly evidence Congress's intention for "medical activity" ("the performance of a medical or surgical procedure on a body") to be patentable. Immunization is an medical activity. The courts reasoning for invalidating Classen's patents under *Bilski* is in conflict with the clear intent of Congress. If the Supreme Court has already struck down the Bilski decision then the court should send this case (*Classen Immunotherapies versus Biogen Idec et al)* back to the CAFC since the criteria for patentability set up by *Bilski* was the sole reason for the ruling of invalidity in this case.

11. *Merck v. Integra* and Proveris Scientific require a reversal of the 271(e), ruling in Classen.

All of the accused activity occurred during commercial exploitation of the vaccines, not during pre-approval development, and none of the Classen patent, are listed in the orange book.

III. These Issues Have Paramount Importance For Patent Litigation And Are Ripe For Review By This Court.

Generic challenges to pharmaceutical patents has increased substantially in recent years in part at the urging of the US government. This has placed a large strain on an over worked court system. Uncertainty in the outcomes is a disincentive to attracting investors needed to develop new pharmaceuticals. There is an need for the court to set a clear message of what is patentable under 35 U.S.C. §101. Furthermore if the court desires to address the issue there is a need to clarify what is the extent of protection under 35 U.S.C. §271(e)1.

The Supreme Court briefly discussed the impact on *Merck Integra* on the infantile research tool industry. The Classen's '283 patent included a research tool a method of testing vaccines for their ability to induce chronic illness. The current decision creates confusion among those in the research tool industry. A clear decision by the Supreme Court could reassure investors and help build this vital industry.

CONCLUSION

The petition for writ of certiorari should be granted.

Respectfully submitted,
ROGER BROWDY
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(any footnotes trail end of each document)

20[illegible]-1634, 2006-1649

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

CLASSEN IMMUNOTHERAPIES, INC.,
Plaintiff-Appellant,
v.
BIOGEN IDEC,
Defendant-Appellee,

and

GLAXOSMITHKLINE,
Defendant-Appellee,

and

MERCK & CO., INC.,
Defendant-Cross Appellant,
and
CHIRON CORPORATION, KAISER-PERMANENTE, INC., KAISER PERMANENTE VENTURES, KAISER PERMANENTE INTERNATIONAL, KAISER PERMANENTE INSURANCE COMPANY, THE PERMANENTE FEDERATION, LLC, THE PERMANENTE COMPANY, LLC, THE PERMANENTE FOUNDATION, THE PERMANENTE MEDICAL GROUP, INC., KAISER FOUNDATION HOSPITALS, KAISER FOUNDATION ADDED CHOICE HEALTH PLAN, INC., and KAISER FOUNDATION HEALTH PLAN INC.,

December 19, 2008, Decided

NOTICE: THIS DECISION WAS ISSUED AS UNPUBLISHED OR NONPRECEDENTIAL AND MAY NOT BE CITED AS PRECEDENT. PLEASE REFER TO FEDERAL RULES OF APPELLATE PROCEDURE RULE 32.1 GOVERNING THE CITATION TO UNPUBLISHED OPINIONS.

Appealed from: United States District Court for the District of Maryland in Case No. 04-CV-2607, Judge William D. Quarles, Jr.

DISPOSITION:

Affirmed.

COUNSEL: Joseph J. Zito, Zito tlp, of Washington, DC, argued for plaintiff-appellant.

Joshua M. Hiller, Wilmer Cutler Pickering Hale and Dorr LLP, of Boston, Massachusetts, for defendant-appellee, Biogen IDEC. On the brief were David B. Bassett, of New York, New York, and David A. Wilson, of Washington, DC.

George F. Pappas, Covington & Burling LLP, of Washington, DC, argued for defendant-appellee, GlaxoSmithKline. With him on the brief were Jeffrey B. Elikan and Kevin B. Collins. Of counsel was Scott C. Weidenfeller.

Mary B. Graham, Morris, Nichols, Arsht & Tunnell, LLP, of Wilmington, Delaware, argued for defendant-cross appellant. With her on the brief was James W. Parrett, Jr. Of counsel on the brief were Robert L. Baechtold, Fitzpatrick, Cella, Harper & Scinto, of New

York, New York; and Edward W. Murray and Mary J. Morry, Merck & Co., Inc., of Rahway, New Jersey.

JUDGES: Before NEWMAN and MOORE, Circuit Judges, and FARNAN, District Judge. *

OPINION BY: MOORE

OPINION

MOORE, *Circuit Judge.*

In light of our decision in *In re Bilski*, 545 F.3d 943 (Fed. Cir. 2008) (en banc), we affirm the district court's grant of summary judgment that these claims are invalid under 35 U.S.C. § 101. Dr. Classen's claims are neither "tied to a particular machine or apparatus" nor do they "transform[] a particular article into a different state or thing." *Bilski*, 545 F.3d at 954. Therefore we *affirm*.

CIVIL NO.: WDQ-04-2607

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND,
NORTHERN DIVISION

CLASSEN IMMUNOTHERAPIES, INC.,
Plaintiff,

v.

BIOGEN IDEC, et al.,
Defendants.

August 16, 2006, Decided

JUDGES: William D. Quarles, Jr., United States District Judge.

OPINION BY: William D. Quarles, Jr.

OPINION

MEMORANDUM OPINION

Classen Immunotherapies, Inc. ("Classen") has sued GlaxoSmithKline ("GSK") and Merck & Co., Inc. ("Merck"), for patent infringement. Merck has counterclaimed, alleging noninfringement and unenforceability of Classen's patents. Pending are: 1) Classen's motions for reconsideration of the Court's December 14, 2005, order and to dismiss Merck's counterclaims; 2) GSK's motion to amend its answer and for summary judgment; and 3) Merck's motions for summary judgment of its counterclaims and to strike

Classen's jury demand. For the following reasons Classen's motion for reconsideration and to dismiss will be denied. GSK's motion to amend will also be denied. Merck's motion for summary judgment will be granted, and its motion to strike Classen's jury demand denied as moot.

I. Background

Classen Immunotherapies, Inc. ("Classen") is a Maryland corporation that has developed and patented methods for evaluating and improving the safety of immunization schedules. Classen is the holder of Patents 6,420,139 (the "139 patent"); 6,638,739 (the "739 patent"); 5,728,385 (the "385 patent"); and 5,723,283 (the "283 patent"). Am. Compl. at Par. 2. Classen alleges that the defendants infringed the patents in question by: 1) examining the correlation between vaccination schedules and the risk of developing chronic immune mediated disorders; and 2) by using the results of that study to develop vaccination protocols. Id at Pars. 6-7.

In its July 22, 2005 order, this Court, inter alia, dismissed Counts I (infringement of the 139 patent), II (infringement of the 739 patent) and IV (infringement of the 283 patent) of the Amended Complaint as to GSK. On December 14, 2005, the Court dismissed Count III (infringement of the 385 patent) as to GSK and Merck and dismissed the counterclaims of invalidity and unenforceability of the 385 patent. The Court also granted summary judgment on Counts I, II, and IV as to Merck. Only Merck's counterclaims of invalidity and unenforceability of the 139, 739 and 283 patents remain.

II. Classen's Motion for Reconsideration

Under Federal Rule of Civil Procedure 59(e), a court may grant a motion for reconsideration to: 1) accommodate an intervening change in controlling law; 2) account for new evidence previously unavailable; or 3) correct a clear error of law or prevent manifest injustice. *Bogart v. Chapell*, 396 F.3d 548 (4th Cir. 2005).

A court may amend a final judgment under Rule 60(b) because of, inter alia: 1) mistake, inadvertence, surprise, or excusable neglect; 2) newly discovered evidence; 3) fraud, misrepresentation, or other misconduct of an adverse party; or 4) any other reason justifying relief from the operation of the judgment. Federal Rule of Civil Procedure, 60(b).

Classen has moved for reconsideration of the Court's December 14, 2005, order arguing that the Court erred in finding no evidence of Merck's infringement of the Classen patents and that newly discovered evidence warrants reconsideration.

The only specific act of infringement alleged in Classen's Amended Complaint was Merck's participation in or facilitation of the 2001 study conducted by Dr. Frank DeStefano which studied the correlation between childhood vaccination and the development of diabetes. As Merck offered uncontroverted evidence that it had no involvement in the DeStefano study, the Court granted Merck's motion for summary judgment. The Court finds no clear error in this decision.

Classen also argues that newly discovered evidence proves Merck's infringement of the Classen patents. Specifically, Classen contends that Merck funded a study to determine whether hepatitis B vaccines increase the risk of multiple sclerosis and has participated in a number of vaccine safety and advisory organizations and advocated their findings.

Discovery in this case closed December 7, 2005. The Court did not grant Merck's motion for summary judgment until December 14, 2005. Even assuming that this evidence proves Merck infringed the Classen patents, Classen has not explained why this evidence was not previously offered. Accordingly, Classen's motion for reconsideration will be denied.

III. GSK's Motion to Amend its Answer

GSK has moved to amend its Answer pursuant to Rule 15(a) in order to assert counterclaims of noninfringement against Classen. GSK has further moved for summary judgment on the counterclaims arguing that GSK, like Merck, had no involvement in the DeStefano Study.

Under Rule 15(a) "a party may amend the party's pleadings only by leave of the court or by written consent of the adverse party; and leave shall be freely given when justice so requires." Motions for leave to file an amended complaint are to be liberally granted in the absence of undue delay, bad faith, dilatory motive, repeated failure to cure deficiencies by amendments previously allowed, undue prejudice to the opposing party, or futility. *Foman v. Davis*, 371 U.S. 178, 182, 83 S. Ct. 227, 9 L. Ed. 2d 222 (1962); see also *Harless v.*

CSX Hotels, 389 F.3d 444 (4th Cir. 2004); *Openshaw v. Cohen, Klingenstein & Marks*, 320 F.Supp.2d 357 (D.Md. 2004).

Classen filed its Amended Complaint in November 2004, alleging infringement of the 139 patent (Count I), the 739 patent (Count II), the 385 patent (Count III), and the 283 patent (Count IV). On July 22, 2005, the Court dismissed Counts I, II, and IV of the Amended Complaint as to GSK. GSK subsequently filed its answer to Count III and counterclaimed arguing noninfringement and patent invalidity of the 385 patent. On December 7, 2005, discovery closed. On December 14, 2005, the Court dismissed Count III of the Amended Complaint with prejudice and GSK's counterclaim without prejudice.

GSK's motion comes more than six months after the claims alleging infringement of the 139, 739 and 283 patent were dismissed and more than a month after the last claim against GSK was dismissed. Given this delay, the fact that the Court has already determined that GSK did not infringe the 139, 739 and 283 patents, and the fact that Classen has not had an opportunity to conduct discovery of the claim, GSK's motion to amend its Answer will be denied.

IV. Classen's Motion to Dismiss Merck's Counterclaims

Classen has moved to dismiss Merck's counterclaims for lack of standing and subject matter jurisdiction pursuant to Federal Rule of Procedure 12(b)(1) and 12(h)(3). Classen argues that the Court's determination that Merck had not infringed the Classen patents moots Merck's counterclaims.

The Supreme Court has held, however, that a determination of noninfringement does not automatically moot a counterclaim for invalidity. *Cardinal Chemical Co. v. Morton International*, 508 U.S. 83, 113 S. Ct. 1967, 124 L. Ed. 2d 1 (1993); see also *Fort James Corporation v. Solo Cup Co.*, 412 F.3d 1340 (Fed. Cir. 2005); *General Electric Co. v. Nintendo Co., Ltd.*, 179 F.3d 1350 (Fed. Cir. 1999). "If...a party has actually been charged with infringement of the patent, there is, necessarily, a case or controversy adequate to support jurisdiction of a complaint or counterclaim." *Cardinal*, 508 U.S. at 96. Accordingly, Classen's motion to dismiss will be denied.

V. Merck's Motion for Summary Judgment on its Counterclaims

Merck has moved for summary judgment arguing that Classen's patents are invalid because they are anticipated by prior art and are an attempt to patent an unpatentable mental process.

An issued patent is presumed valid and the burden is on the party challenging the validity of a patent to show that it is invalid by clear and convincing evidence. *Minnesota Mining and Manufacturing, Co.*, 303 F.3d 1294 (Fed. Cir. 2002).

Under Rule 56(c), summary judgment is appropriate when there is no genuine issue of material fact, and the moving party is entitled to judgment as a matter of law. *Celotex Corp. v. Catrett*, 477 U.S. 317, 322, 106 S. Ct. 2548, 91 L. Ed. 2d 265 (1986). A dispute about a material fact is genuine "if the evidence is such that a reasonable jury could return a verdict for the

nonmoving party." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248, 106 S. Ct. 2505, 91 L. Ed. 2d 202 (1986). In considering a motion for summary judgment, "the judge's function is not . . . to weigh the evidence and determine the truth of the matter but to determine whether there is a genuine issue for trial." *Id* at 249. Thus, "the judge must ask . . . whether a fair-minded jury could return a verdict for the [nonmoving party] on the evidence presented." *Id.* at 252.

The court must view the facts and reasonable inferences drawn therefrom "in the light most favorable to the party opposing the motion." *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587, 106 S. Ct. 1348, 89 L. Ed. 2d 538 (1986). However, the opposing party must produce evidence upon which a reasonable fact finder could rely. *Celotex Corp. v. Catrett*, 477 U.S. 317, 106 S. Ct. 2548, 91 L. Ed. 2d 265 (1986). The mere existence of a "scintilla" of evidence is insufficient to preclude summary judgment. *Anderson*, 477 U.S. at 252.

A. Anticipation

A patent claim is invalid by reason of anticipation if "the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent..." 35 U.S.C. § 102(a). Whether a patent claim has been anticipated is a question of fact. *Minnesota Mining and Manufacturing, Co.*, 303 F.3d at 1301.

For prior art to anticipate because it has been "used," the use must be accessible to the public. Id. Public use

includes any use of the claimed invention by a person other than the inventor who is under no limitation, restriction or obligation of secrecy to the inventor. *Id.*

Merck argues that the 139, 739 and 283 patents are invalid because they have been anticipated by prior art. Specifically, Merck argues that the method for developing vaccine schedules claimed in the Classen patents and the vaccine schedule for Recombivax HB were already in use when the Classen patents were approved.

The 283 patent requires determining whether an immunization schedule affects the incidence of a chronic immune-mediated disorder by immunizing a treatment group and comparing the incidence of immune-mediated disorders to that of a control group. 283 Patent, Claim 1. Both the 139 and 739 patents require comparing the incidence of immune-mediated disorders in in treatment groups with different vaccination schedules and immunizing patients on a schedule identified as low risk. 139 Patent, Claim 1; 739 Patent, Claim 1.

As the Classen patents cover a process by which lower risk vaccine schedules are identified, the fact that the current Recombivax HB vaccination schedule was in use at the time the Classen patents were approved does not prove that the patented process was anticipated by prior art. In addition, Merck has offered no evidence that Classen's method for determining the safety of vaccine schedules was in use when the Classen patents were approved. Although a 1987 Journal of the American Medical Association article reports that "no significant adverse effects were reported that could be

attributed to...the [Recombivax HB] vaccine," there is no evidence that the correlation between immune-mediated disorders and the vaccine was evaluated. Def.'s Motion for Summary Judgment, Ex. I, p. 4. As there remains a genuine issue as to whether the Classen's patents were anticipated by prior art, Merck's motion for summary judgment on the grounds of anticipation will be denied.

B. Unpatentability

Under 35 U.S.C. § 101, "whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore." Excluded from patent protection, however, are "laws of nature, natural phenomenon and abstract ideas." *Diamond v. Diehr*, 450 U.S. 175, 185, 101 S. Ct. 1048, 67 L. Ed. 2d 155 (1981); see also *Diamond v. Chakrabarty*, 447 U.S. 303, 309, 100 S. Ct. 2204, 65 L. Ed. 2d 144 (1980); *Parker v. Flook*, 437 U.S. 584, 98 S. Ct. 2522, 57 L. Ed. 2d 451 (1978); *Gottschalk v. Benson*, 409 U.S. 63, 93 S. Ct. 253, 34 L. Ed. 2d 273 (1972).

Einstein could not patent his celebrated law that E=MC<2>; nor could Newton have patented the law of gravity. Such discoveries are manifestations of nature free to all men and reserved exclusively to none.

Diehr, 450 U.S. at 185 (citing *Chakrabarty*, 447 U.S. at 309). When a claim contains a natural phenomenon, the court must determine whether the claim is merely seeking to patent the phenomenon itself by describing it in abstract process terms. *Id* at 192.

In determining whether a claimed process is eligible for patent protection under § 101, courts must consider the patent claims as a whole. *Id* at 188. "A new combination of steps in a process may be patentable even though all the constituents of the combination were well known and in common use before the combination was made." *Id.* However, "[i]nsignificant post-solution activity will not transform an unpatentable principle into a patentable process." *Id.*

Merck argues that the Classen patents are unpatentable because they involve "thinking about" whether a vaccination schedule reduces the incidence of chronic disease and, therefore, seek to patent an abstract mental process about a natural phenomenon. Classen argues that the patents at issue do not claim a scientific truth, but instead describe a method for reducing the incidence of chronic immune mediated disorders.

Clearly, the correlation between vaccination schedules and the incidence of immune mediated disorders that Dr. Classen claims to have discovered is a natural phenomenon. The issue, therefore, is whether the Classen patents simply describe this correlation.

The 283 patent claims "a method of determining whether an immunization schedule affects the incidence or severity of a chronic immune-mediated disorder in a treatment group of mammals, relative to a control group of mammals." 283 Patent, Claim 1. The method described by the 283 patent involves: 1) immunization of a treatment group; and 2) a comparison of the incidence of chronic immune mediated disorders in the treatment group relative to a control group. Id.

Although articulated as a process, the 283 patent does not claim a specific technique or technical process of testing vaccine safety. Instead, the 283 patent describes only a general inquiry of whether the proposed correlation between an immunization schedule and the incidence of chronic disorders exists. As such, the process is indistinguishable from the idea itself. Accordingly, the 283 patent seeks to patent an unpatentable natural phenomenon.

Both the 139 and 739 patents claim "a method of immunizing a mammalian subject" which requires: 1) comparing the incidence of immune mediated disorders in treatment groups with different vaccination schedules; and 2) immunizing patients on a schedule identified as low risk. 139 Patent, Claim 1; 739 Patent, Claim 1.

Although described as a process for immunizing "mammalian subjects", the 139 and 739 patents do not describe a particular vaccine or vaccine schedule. Instead, the 139 and 739 patents describe a process by which different immunization schedules are compared and the schedule which has the lowest correlation to chronic disorders is selected. Like the 283 patent, the 139 and 739 patents describe little more than an inquiry of the extent of the proposed correlation between vaccines and chronic disorders. Although the 139 and 739 patents include the active step of immunizing patients in accordance with a schedule determined to be low risk, as noted above, "[i]nsignificant post-solution activity will not transform an unpatentable principle into a patentable process." *Diehr*, 450 U.S. at 192. As it would appear that the 139 and 739 patents are an indirect attempt to patent the idea that there is a

relationship between vaccine schedules and chronic immune mediated disorders, the Court finds they are an attempt to patent an unpatentable natural phenomenon.

C. Conclusion

As the Court finds that the 283, 139 and 739 patents seek to patent unpatentable subject matter, Merck's motion for summary judgment on its counterclaim for invalidity will be granted.

VI. Merck's Motion to Strike Classen's Jury Demand

Merck has moved to strike Classen's jury demand. As the Court will grant summary judgment of Merck's counterclaim, the motion will be denied as moot.

VII. Conclusion

For the reasons stated above, Classen's motion for reconsideration and to dismiss will be denied. GSK's motion to amend will also be denied. Merck's motion for summary judgment will be granted, and its motion to strike Classen's jury demand denied as moot.

August 16, 2006

Date

/s/

William D. Quarles, Jr.

United States District Judge

Filed: 12/14/05
CIVIL NO.: WDQ-04-2607

UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MARYLAND, NORTHERN DIVISION

CLASSEN IMMUNOTHERAPIES, INC.,
Plaintiff,

v.

BIOGEN IDEC, et al.,
Defendants.

Memorandum Opinion

Classen Immunotherapies, Inc. ("Classen"') has sued Biogen IDEC ("Biogen"), GlaxoSmithKline ("GSK-"') , and Merck & Co. , Inc. , for patent infringement. Biogen, GSK and Merck have counterclaimed, alleging noninfringement and unenforceability of Classen's patents. Pending are Classen's motions for reconsideration of the Court's July 22, 2005 opinion; voluntary dismissal of Count III of the Complaint; discovery; to stay discovery; to strike miscellaneous correspondence; and to amend the scheduling order. Also pending is Merck's motion for summary judgment.

For the following reasons, Classen's motion to dismiss Count III and Merck's motion for summary judgment will be granted. Classen's motions for discovery, to stay discovery, to strike miscellaneous correspondence and to amend the scheduling order will be denied.

I. Background

Classen Immunotherapies, Inc. ("Classen"') is a Maryland corporation that has developed and patented methods for evaluating and improving the safety of immunization schedules. Classen is the holder of Patents 6,420,139 (the "139 patent"); 6,638,739 (the "739 patent") ; 5,728,385 (the "385 patent") ; and 5,723,283 (the "283 patent") . Am. Compl. at Par. 1 2. Classen alleges that the defendants infringed the patents in question by studying the correlation between vaccinations schedules and the risk of developing chronic immune mediated disorders, and by using the results of that study to develop vaccination protocols. Id at Pars. 6-7.

In its July 22, 2005 order, this Court, inter alia, dismissed Counts I (infringement of the 139 patent), II (infringement of the 739 patent) and IV (infringement of the 283 patent) of the Amended Complaint as to Biogen and GSK. All Counts remain as to Merck; Count III (infringement of the 385 patent) remains as to Biogen and GSK.

II. Classen's Motion for Partial Reconsideration

Classen has moved for reconsideration of the Court's order dismissing Counts I, II, and IV as to Biogen and GSK, arguing that the Court misinterpreted 35 U.S.C. § 271(e) and the Supreme Court's opinion in Merck v. Integra, 125 S. Ct. 2372 (2005). As the Court finds neither a clear error of law, nor a change in the controlling law, Classen's motion for partial reconsideration will be denied.

III. Classen's Motion for Voluntary Dismissal of Count III Pursuant to Federal Rule of Civil Procedure 41(a)(2) or Rule 15, Classen has moved to: 1) voluntarily dismiss Count III of the Complaint with prejudice as to GSK, Biogen and Merck, and to dismiss the Defendants' counterclaims as to the 385 patent without prejudice.

As Defendants do not oppose Classen's motion[1], and no prejudice to the Defendants will result, Count III of the Complaint will be dismissed with prejudice as to all defendants. Defendants' counterclaims as to the 385 patent will be dismissed without prejudice.

Accordingly, Biogen and GSK will be dismissed from the case. Counts I, II and IV remain as to Merck.

IV. Merck's Motion for Summary Judgment

Merck has moved for summary judgment arguing that: 1) Merck did not participate in the study alleged to have infringed Classen's patents; and 2) Merck's vaccine schedule differs from Classen's recommended schedule.

Under Rule 56(c), summary judgment is appropriate when there is no genuine issue of material fact, and the moving party is entitled to judgment as a matter of law. Celotex Corp. v. Catrett, 477 U.S. 317, 322 (1986). A dispute about a material fact is genuine "if the evidence is such that a reasonable jury could return a verdict for the nonmoving party." Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986). In considering a motion for summary judgment, "the judge's function is not . . . to weigh the evidence and determine the truth of the matter but to determine whether there is a genuine

issue for trial." Id. at 249. Thus, "the judge must ask . . . whether a fair-minded jury could return a verdict for the [nonmoving party] on the evidence presented." Id. at 252.

The court must view the facts and reasonable inferences drawn therefrom "in the light most favorable to the party opposing the motion." Matsushita Elec. Indus. Co. v. Zenith Radio Corp., 475 U.S. 574, 587 (1986). However, the opposing party must produce evidence upon which a reasonable fact finder could rely. Celotex Corp. v. Catrett, 477 U.S. 317 (1986). The mere existence of a "scintilla" of evidence is insufficient to preclude summary judgment. Anderson, 477 U.S. at 252.

The 283 patent requires: 1) the immunization of a treatment group; 2) a comparison of the incidence of immune mediated disorders in the treatment group and a control group. 283 Patent, Claim 1. Both the 139 and 739 patents require: 1) screening immunization schedules by comparing incidence of immune mediated disorders in treatment groups with different vaccination schedules; and 2) immunizing patients on a schedule identified as low risk. 139 Patent, Claim 1; 739 Patent, Claim 1.

Classen contends that Merck infringed the 283, 139, and 739 patents by participating in a study, published in December, 2001, that evaluated the correlation between vaccination schedules and the incidence of chronic immune mediated disorders. Am. Compl. Pl. 7. However, according to Dr. Frank DeStefano, the author of the 2001 study, the study was led and sponsored by the Centers for Disease Control and

Prevention (CDC). DeStefano Affidavit, Pars. 2-3. Dr. DeStefano avers that Merck had no involvement, at any time, in any part of the study or the published article. Id at Par. 3.

Classen has offered no evidence disputing Dr. Stefano's assertion, nor has it offered any evidence linking Merck to any other study or evaluation of the correlation between vaccination schedules and incidents of immune mediated disorders. As Classen's claims rely on Merck's participation in or inducement of an examination of the correlation between vaccine schedules and immune mediated disorders, Merck's motion for summary judgment as to Counts I, II and IV of the Complaint will be granted.

As all counts of Classen's complaint have been or will be dismissed as to all defendants, only Merck's counterclaims remain pending.

V. Classen's Motion for Discovery and to Stay Discovery

As discovery has ended, Classen's motions for discovery and to stay discovery will be denied as moot.

VI. Classen's Motion to Strike Miscellaneous Correspondence As all counts have been or will be dismissed as to GSK, Classen's motion to strike GSK's July 19, 2005 correspondence will be denied as moot.

VII. Classen's Motion to Amend the Scheduling Order

Classen has moved to amend the scheduling order to allow the designation of two experts. The deadline for

designation of Plaintiff's experts was September 23, 2005 and November 7, 2005 for rebuttal experts. As Classen has had ample time to designate its experts, but has failed to do so, the motion to amend the scheduling order will be denied.

Footnote

[1] Merck has agreed not to oppose the Motion if Classen will stipulate that it will not bring any claim for infringement of the 385 patent against Merck for any vaccine Merck currently manufactures, distributes, or has marketed or distributed in the past.

Filed 2/9/2009
2006-1634, 2006-1649
UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

CLASSEN IMMUNOTHERAPIES, INC.,
Plaintiff-Appellant,
v.
BIOGEN IDEC, et al

Combined Petition for Panel Rehearing and Rehearing En Banc.

ORDER

Denied.

OPPOSITION BRIEF

Supreme Court, U.S.
FILED
AUG 7 - 2009
OFFICE OF THE CLERK

No. 08-1509

IN THE

Supreme Court of the United States

CLASSEN IMMUNOTHERAPIES, INC.,
Petitioner,

v.

BIOGEN IDEC, GLAXOSMITHKLINE,
AND MERCK & CO., INC.,
Respondents.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

BRIEF FOR RESPONDENT GLAXOSMITHKLINE IN OPPOSITION

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August 2009

RULE 29.6 CORPORATE DISCLOSURE STATEMENT

Respondent SmithKline Beecham Corporation, d/b/a GlaxoSmithKline, is a wholly owned subsidiary of GlaxoSmithKline plc. No other publicly held corporation owns 10 percent or more of the stock of Respondent.

STATEMENT

1. Petitioner Classen Immunotherapies, Inc. ("Classen") sued Respondents Biogen IDEC ("Biogen"), GlaxoSmithKline ("GSK"), and Merck & Co., Inc. ("Merck") for patent infringement. Pet. App. 4a. Classen developed and patented methods for evaluating and improving the safety of immunization schedules. *Id.* at 5a. Classen alleges that Respondents infringed its patents by (i) examining the correlation between vaccination schedules and the risk of developing chronic immune mediated disorders, and (ii) using the results of that study to develop vaccination protocols. *Id.*

2. The district court (D. Md., Quarles, J.) entered judgment for Respondents. In July 2005, the court granted a motion by Respondents GSK and Biogen to dismiss Classen's claims based on the exemption in 35 U.S.C. § 271(e)(1). Section 271(e)(1) provides, in relevant part:

> It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention . . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.

The district court noted this Court's statement in *Merck KgaA* v. *Integra Lifesciences I, Ltd.*, 545 U.S. 193, 202 (2005), that Section 271(e)(1) "provides

a wide berth for the use of patented drugs in activities related to the federal regulatory process." The district court determined that Respondents' "alleged participation in a study evaluating risks associated with various vaccination schedules was reasonably related to the development and submission of information required under the Federal Food, Drug and Cosmetic Act," and therefore granted Respondents' motion to dismiss three of the four counts of patent infringement. The district court subsequently granted Classen's motion to dismiss the remaining count of its complaint, with prejudice. Pet. App. 17a-18a.

In December 2005, the district court granted Merck's motion for summary judgment. The court determined that Classen had failed to offer any evidence linking Merck to a study published in December 2001 (the "DeStefano Study"), or to any other study or evaluation of the correlation between vaccination schedules and incidents of immune mediated disorders, and therefore Classen could not prevail on its infringement claims. *Id.* at 19a-20a.

In August 2006, the district court granted summary judgment on Merck's counterclaim for invalidity. Pet. App. 12a-15a. The court based its analysis on the principle that patent protection is not available for "laws of nature, natural phenomen[a] and abstract ideas." *Id.* at 12a, quoting *Diamond* v. *Diehr*, 450 U.S. 175, 185 (1981) (additional citations omitted). The court noted that "[c]learly, the correlation between vaccination schedules and the incidence of immune mediated disorders that Dr. Classen claims to have discovered is a natural

phenomenon. The issue, therefore, is whether the Classen patents simply describe this correlation." Pet. App. 13a. The court then considered each of Classen's three patents in turn and held that they each seek to patent a natural phenomenon. Pet. App. 14a-15a.

3. The court of appeals affirmed. Pet. App. 3a. The Federal Circuit noted that Classen's claims "are neither 'tied to a particular machine or apparatus' nor do they 'transform[ ] a particular article into a different state or thing.'" *Id.* (quoting *In re Bilski*, 545 F.3d 943 (Fed. Cir. 2008) (en banc)).

REASONS FOR DENYING THE PETITION

Petitioner urges the Court to hold its petition pending a decision in *Bilski* v. *Doll*, No. 08-964, *cert. granted* 556 U.S. __ (June 1, 2009). Because the result in this case will not change based on this Court's decision in *Bilski*, the petition should be denied.

The district court held that Classen failed to present any evidence that Merck infringed the patents. Pet. App. 20a. That holding provides a reason to deny the petition for certiorari. Because GSK, like Merck, had no involvement in the DeStefano Study that Classen relies on as the basis for its claims, the absence of evidence of infringement provides a sufficient basis for denying the petition. GSK would allege noninfringement if this case were remanded and, based on Merck's success with this argument below, GSK would likely prevail.

In any event, any potentially infringing studies conducted by GSK would have been exempt from any allegation of patent infringement under 271(e)(1) as determined by the District Court.[1]

Finally, the general method set out in the Classen patent claims litigated below[2] simply covers a basic technique of all clinical trials: comparing a method of treatment to a control and then thinking about the results. Classen has not invented a new vaccine, vaccine schedule, or method for administering vaccines. Any determination that one schedule is safer than the other therefore is simply the recognition of an inherent property of the prior art schedule. For this reason, the patent claims

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[1] Following the district court's ruling, the Federal Circuit issued a decision in another case holding that Section 271(e) does not immunize the manufacture, marketing or sale of a patented invention that is "used in the development of FDA regulatory submissions but is not itself subject to the FDA premarket approval process." *Proveris Scientific Corp.* v. *Inovasystems, Inc.*, 536 F.3d 1256, 1265 (Fed. Cir. 2008). Any potentially infringing study conducted by GSK comparing the safety of two vaccination schedules would fall within the 271(e) safe harbor because GSK would be required to report any adverse events to the FDA even after approval. Given that GSK would be required to report such events to the FDA, the Federal Circuit's decision in *Proveris Scientific* does not apply to these facts. Whether 271(e) applies to testing results which are obtained through standard clinical design and which must be reported to the FDA is, at a minimum, a question that should be considered by the Federal Circuit in the first instance.

[2] Classen did not argue below that any dependent claims contained additional limitations relevant to the validity of his patents.

should be considered anticipated under 35 U.S.C. § 102.

CONCLUSION

The petition for a writ of certiorari should be denied because it does not present issues that are ripe or well presented for consideration by this Court. In the alternative and at a minimum, the Court should delay any consideration of this petition pending a decision on the merits in *Bilski* v. *Doll*, and then dispose of the petition as appropriate.

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OPPOSITION BRIEF

(3)

No. 08-1509

Supreme Court, U.S.
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IN THE

Supreme Court of the United States

CLASSEN IMMUNOTHERAPIES, INC.,

Petitioner,

v.

BIOGEN IDEC, GLAXOSMITHKLINE, AND MERCK & CO., INC.,

Respondents.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

BRIEF IN OPPOSITION FOR RESPONDENT MERCK & CO., INC.

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QUESTIONS PRESENTED

This is not, as Classen asserts (Pet. 2), "a case about patentability of methods of using pharmaceuticals and medical activities." Classen did not invent a new pharmaceutical, a new method of using a pharmaceutical or a new medical practice. Rather, taking Classen's own description of his "invention" at his word, "the patents are collectively about (i) *comparing* two or more vaccination schedules [e.g. immunizing at different ages], (ii) *determining* if one or more schedules has a lower associated risk [e.g. of later developing a chronic disease], and (iii) immunizing according to a lower risk schedule." (Pet. 9) (emphasis added). The supposed invention lies in the mental steps of "comparing" and "determining" because, as Classen concedes, the physical step of immunizing is old.

Classen's underlying theory that the age of immunization has an effect on the incidence of chronic diseases has been discredited. But, even if true, the mental process of thinking about the possible impact of the timing of immunization is not patentable subject matter. Thus, contrary to Classen's assertion, this case does not have wide impact in the pharmaceutical and medical fields or diverge from longstanding precedent of this Court.

Moreover, deciding whether Classen's "invention" meets the requirements of 35 U.S.C. § 101 would be futile because his patent claims do not define anything new. Comparing the risks and results of alternative protocols is something physicians have always routinely done. And Classen's patent claims, according to his own

characterization, cover the prior art, routine medical practice of immunizing with a known vaccine according to an existing schedule merely because that old schedule is now believed to be safer than some other protocol.

This case does not turn on the outcome of *In re Bilski*. Well before the decision in *Bilski*, it was beyond dispute that a mental process is not patentable. Thus, this case does not present any unsettled question of law, let alone one of general interest or application.

The only question actually presented is one answered long ago in this Court's prior decisions:

Is an "invention" patentable where its only distinction over the prior art is a mental step of recognizing benefits inherent in that prior art?

RULE 29.6

Merck & Co., Inc. is a publicly held corporation. It has no parent corporation and no publicly held company owns 10% or more of Merck's stock.

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INTRODUCTION

Classen's petition does not present a compelling reason for grant of certiorari under Supreme Court Rule 10.[1] Consistent with longstanding precedent of this Court, including *Funk Bros.*, *Benson*, *Flook*, *Diehr* and *Chakrabarty*, the District Court held, and the Federal Circuit affirmed, that Classen's patents were invalid under 35 U.S.C. § 101 because his alleged invention was not patentable subject matter. In doing so, the Federal Circuit did not decide "an important question of federal law that has not been, but should be, settled by this Court;" nor did it decide "an important federal question in a way that conflicts with relevant decisions of this Court." *See* Supreme Court Rule 10(c).

Classen asks for a stay pending the outcome of *In re Bilski*[2] cited by the Federal Circuit in affirming the invalidity of Classen's patents and then, if this Court were to reverse *Bilski*, for this case to be sent back to the Federal Circuit. (Pet. i, 3). But regardless of the

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[1] In this brief, "Classen" is used interchangeably to refer to the individual and named inventor, John Barthelow Classen, and his company, the plaintiff Classen Immunotherapies, Inc. The two are effectively one and the same. (A1456-58 at 245, 248-52).

Citations in the form: "Pet. __" are to pages of Classen's Petition for a Writ of Certiorari; "A __" are to pages of the parties' Joint Appendix in the Federal Circuit; and "Classen Op. App. Br. __" are to pages of Classen's opening brief on appeal to the Federal Circuit (filed 11/20/2006).

[2] 545 F.3d 943 (Fed. Cir. 2008), *cert. granted*, 129 S. Ct. 2735 (2009) (No. 08-964)

outcome of this Court's consideration of *Bilski's* "machine-or-transformation" test, it would be a waste of judicial and party resources to remand this case to the Federal Circuit or otherwise give it further consideration, as the judgment of invalidity of Classen's patents must stand under this Court's well-established holdings, regardless of *Bilski*. The distinguishing feature of Classen's "invention," by his own characterization, is a mental process involving an abstract idea (and one that has been decisively discredited). Such an "invention" is not, and has never been, patentable under any court's view of Section 101.

Thus, if Classen's petition were granted, this Court would not reach the general questions posed by Classen (Pet. 2) of the patentability of "medical activities" and "methods of using pharmaceuticals," or the effect of *Bilski* on the patents of others. Further review of Classen's patents would not provide any greater assistance for other cases than is already present in this Court's long history of cases dealing with nonpatentable subject matter. The patent bar evidently recognizes that further consideration of Classen's patents will not lead to helpful guidance and that the case does not have the potential for meaningful impact on other patents, for despite Classen's efforts to recruit *amicus curiae* support for his case, no one has stepped forward.

Finally, this case does not warrant review by this Court because, regardless of how the issue under Section 101 is framed or analyzed, the judgment of invalidity would be compelled on the alternative ground of anticipation, as Merck set forth in its motion for summary judgment. As a consequence, even if this Court

were to hold that both courts below had erred in applying the law of Section 101, the ultimate judgment of invalidity would still stand.

STATEMENT OF CASE

A. Classen's "Discovery"

Classen's patents stem from his alleged "discovery," based on limited and statistically questionable data, that early immunization against infectious disease reduces the risk of later development of chronic disease. More specifically, according to Classen, immunizing with a vaccine against infectious disease starting before the first six to eight weeks of life is associated with a decreased risk of chronic disease while immunizing starting after that time is associated with increased risk. (A105, col. 9, ll. 13-26). The chronic diseases allegedly implicated include diabetes, asthma, hay fever, various cancers and a host of others. (A105, col. 10).

The actual patent coverage that Classen received for his "discovery" is not limited to any specific or even known vaccine, any specific age of inoculation, or any specific chronic adverse effect. (A1455 at 115-16, A1460-62). Rather, his patent claims are directed to the broad concept of comparing any schedules for administering any vaccine, determining which gives a lower incidence of risk of any chronic disease, and choosing the one that is safer.

Classen's petition states that his "research was aired by ABC" and "fueled a debate in the medical community." (Pet. 5). Although Classen's claimed

"discovery" of a threat to human health from routine vaccinations did trigger investigation, the extensive research then conducted by the medical and public health communities rejected that claim.

The Centers for Disease Control and Prevention ("CDC"), under the direction of Frank DeStefano, M.D., a medical epidemiologist in its Immunization Safety Office, conducted a scientifically sound, retrospective, case-controlled study of health maintenance organization patient records to test Classen's theory and "to determine whether timing of [childhood] vaccination[s] influences risk [of developing diabetes]." (A1087-94 at A1089). Dr. DeStefano conducted this study in collaboration with scientists from the Center for Health Research, the Kaiser Foundation Hospital, the Center for Vaccine Research, the Pediatric Vaccine Study Center, the Center for Health Studies and the Vaccine Safety Datalink Team. (A1093).[3] It was "the first epidemiologic study to evaluate the possibility that timing of vaccination is related to risk of clinical diabetes in children." (A1092). This study concluded that Classen's theory is "unfounded":

> The results of our study and the preponderance of epidemiologic evidence *do*

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[3] Classen's Petition asserts that Merck "sponsored and conducted many studies and evaluations to test Dr. Classen's work and to evaluate the risks and benefits associated with vaccine schedules" and "sponsored meetings and publications to disseminate these findings." (Pet. 5). No support exists in the record for these assertions and the district court granted Merck summary judgment of noninfringement. Moreover, Classen offered no evidence below that anyone at Merck ever believed or expressed belief in Classen's theory.

> *not support an association between any of the recommended childhood vaccines and an increased risk of type 1 diabetes. Suggestions that diabetes risk in humans may be altered by changes in the timing of vaccinations also are unfounded.*

(A1093) (emphasis added). The CDC also published for the general public an assessment of Classen's "discovery," concluding that "carefully performed scientific studies show that vaccines do not cause diabetes or increase a person's risk of developing diabetes," and "the only evidence suggesting a relationship" comes from studies of Classen, which "have a number of limitations and have not been verified by other researchers." (A1035-40 at 1036-37).[4]

The Federal Drug Administration considered, and rejected, Classen's "discovery." (A1042-58 at A1051) (panel of public health experts concluding that the "data are insufficient to establish a causal relationship between any childhood vaccines and . . . the risk of [diabetes]").

Other respected scientists in the medical community similarly concluded that Classen's "discovery" is not supported. Dr. Paul Offit at Children's Hospital of Philadelphia, University of Pennsylvania School of Medicine, concluded that, "[t]he best available evidence does not support the hypothesis that vaccines cause type 1 diabetes." (A382); *see also* (A1482-96) (similar conclusions noted).

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[4] For example, the CDC notes that Classen appeared to employ "highly questionable" "'post-hoc' statistical testing." (A1038).

The United States Court of Claims has rejected Classen's "discovery." *Baker v. Sec'y of Dept. of Health & Human Servs.*, No. 99-653V, 2003 U.S. Claims LEXIS 290, at *95 (Fed. Cl. Sept. 26, 2003) (finding "overwhelming evidence in epidemiologic and medical articles, based on extensive research in various countries, concluding that there is no valid proof that childhood vaccinations cause IDDM [diabetes.]"). (A1060-86). *See also, Meyers v. Sec'y of Dept. of Health & Human Servs.*, No. 04-1771V, 2006 WL 1593947 (Fed. Cl. May 22, 2006).

No company has taken a license and no one has paid any compensation for rights to Classen's patents. (A1451-52 at 39-43).

B. Classen's Patents

The '139 and '739 patents claim a two-step method: "screening" of immunization schedules against infectious disease to determine a schedule with lower risk than others of causing a chronic disease, and then "immunizing" someone according to that lower-risk schedule. (Classen Op. App. Br. 6). The '283 patent claims "comparing" and "determining" whether an immunization schedule affects the incidence or severity of a chronic disease by first "immunizing" a treatment group and a control group, and then "comparing" the incidence of the disease in the two groups. (Classen Op. App. Br. 7).

Nothing is new in Classen's "immunizing" step, as Classen's claimed invention does not require that a new immunization schedule result from "screening," or from

"comparing" and "determining." Rather, as Classen admits, his process "may *confirm* that *the current schedule* is the low risk schedule." (A1165) (emphasis added). Similarly, "[i]f the risk assessment demonstrates that the current schedule is the low risk schedule, *maintenance of the current schedule is step (II) [immunizing] of the Classen method.*" (Classen Op. App. Br. 7) (emphasis added). Indeed, according to Classen, the medical community infringes his patents by immunizing with Merck's hepatitis B vaccine in accordance with a standard schedule. But that act of immunizing is not new, as Merck's vaccine and that schedule were both in the prior art. (A1498-502; A1594-600; A1502-06).

By Classen's own characterizations, the steps of his patent claims other than "immunizing" (i.e. "screening" in the '139 and '739 patents, and "comparing" and "determining" in the '283 patent) are broad enough to encompass merely *thinking about*, without any physical act, the alleged benefit of a schedule in comparison to some other schedule. This mental process of considering the risks of different schedules and choosing the safer one – whether early, late or otherwise – is the distinguishing feature of Classen's claimed process over the admitted prior art of "immunizing:"

- "*The thrust of the present invention is not the development of methods of immunizing* against infectious disease, . . ." (A1461) (emphasis added).

- "[A]nyone who *considers* the data in [others'] papers and then immunizes according to a schedule which may be associated with a

decreased risk is a direct infringer." (A1465) (emphasis added)

- The step of "determin[ing] the affect [*sic* effect] of an immunization schedule on the incidence or severity of a chronic immune-mediated disorder . . . [is met] by *reviewing* studies conducted by others" that "compare the incidence, prevalence, frequency or severity of a chronic immune-mediated disorder" in a treatment group with people in a control group. (A1470-71) (emphasis added).

- "By *reading the comparisons* and then immunizing one will infringe . . . ." (A1827) (emphasis added).

- "[*S*]*creening of the trials, papers, records and/or studies of others* is sufficient for the first step of infringement." (A1164) (emphasis added).

- "In order to infringe the claims of the patents in suit, the infringer need only assess the risk, step (I). It is *not necessary for the infringer to conduct its own clinical trials* or to prove the cause of any risks." (Classen Op. App. Br. 7, 41) (emphasis added).

- "[D]isseminating [ ] books" that "induce[ ] readers to compare risks of different schedules prior to choosing an immunization schedule" "induces infringement." (Classen Op. App. Br. 18).

- Infringement occurs when a "health care provider *reads the relevant literature and selects an immunization schedule* and immunizes." (Classen Op. App. Br. 22) (emphasis added).

- Screening is performed by being "*aware* of the Classen papers" and other studies and commentary. (Classen Op. App. Br. 48) (emphasis added).

Thus, to use Classen's patented "invention," it is not necessary for the infringer to conduct its own clinical trials or to engage in any other physical activity to assess risk (A1163; Classen Op. App. Br. 41), and it is not necessary that the thought process result in a new immunization schedule not in the prior art (A1159, A1163; Classen Op. App. Br. 7). Nor is it necessary that the practitioner alter his or her long-standing medical practice which, prior to thinking about Classen's theory, was non-infringing.

That Classen's patented "invention" is purely a mental exercise is apparent from a simple analysis. He claims to have discovered that it is even more beneficial than previously thought to vaccinate an infant at an early age, e.g. prior to the first six to eight weeks of life. But he could not possibly claim that as a new method of immunization because early immunization was recommended for Merck's hepatitis B vaccine well before Classen's patent applications. Unable to claim the method of actually immunizing infants, Classen turned to claiming methods for thinking about immunizing them. Therefore, he casts his "invention" as comparing

that long-practiced schedule against some different schedule (which could also be an old schedule), deciding which is better, and then "choosing" the safer one with respect to risk of later chronic disease, which then happens to be the conventional schedule already in use. In other words, the only thing that purportedly distinguishes his "invention," and determines whether his claims cover some specific activity, is the mental process of "comparing" and "choosing." Apart from the lack of novelty in choosing among different methodologies based on safety, which has been standard medical practice since at least the days of Hippocrates ("above all, do no harm"), that purely mental exercise is not patentable subject matter.

Classen's patents are not, as his petition seeks to represent, like typical immunization or other medical patents, which involve new physical steps or new pharmaceutical agents. Classen's own interpretation of his "invention" as directed to a mental process of thinking about an alleged benefit (with no new vaccine, no new schedule and no new physical way of immunizing) is what led to the district court's judgment of invalidity and the Federal Circuit's affirmance.

Classen's argument that the district court committed an "error[] in law" in "making a broad sweeping characterization of the patents without considering the additional limitations of the dependant claims" (Pet. 8-9) fails because he did not argue in the district court that the dependent claims had further limitations relevant to the validity of his patents. (*See* A1558-74). In response to the Federal Circuit's specific inquiry at oral argument, Classen was unable

to point to any place in the district court record where he had argued the limitations of any dependent claim in opposing summary judgment of invalidity. (Post-hearing letters to Federal Circuit of August 31, 2007 from Classen and of September 12, 2007 from Merck in response to Classen). Classen chose instead to rely on the broad claim 1 of each patent, and his own "sweeping" interpretation of his alleged invention, and it was his interpretation which formed the basis for the district court's summary judgment of invalidity.[5]

Having failed to raise an issue of the dependent claims with the district court, Classen is precluded from doing so on appeal. *Hormel v. Helvering*, 312 U.S. 552, 556 (1941) ("Ordinarily an appellate court does not give consideration to issues not raised below."); *see also Conoco, Inc. v. Energy & Envtl. Int'l L.C.*, 460 F.3d 1349, 1358-59 (Fed. Cir. 2006).

REASONS FOR DENYING THE PETITION

This case does not present an unsettled question of law or a question of law that conflicts with this Court's jurisprudence. Classen's "invention" of a mental process falls squarely within subject matter that is not patentable. Both lower courts agreed.

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[5] Classen originally relied on his "sweeping" characterizations of his patent claims for his broad allegations of infringement. Merck did not contest Classen's claim construction for purposes of summary judgment, but reserved any rights to contest it in the event that summary judgment did not end the case.

The District Court relied on Classen's own characterization of his claimed invention. Classen has admitted that the district court applied his claim construction: "[The district] court [made] a decision on the interpretation of the claims consistent with the inventor's intended meaning." (Classen Op. App. Br. 11, n.2). In resolving Classen's appeal, the Federal Circuit similarly accepted Classen's interpretation. Thus, if this Court were to grant certiorari, it would likewise be assessing the patents on that basis. The answer to the patentability of a mental process such as Classen's "invention" was settled by this Court long ago. Such a process is not patentable.

Classen's effort to make his case appear compelling for the grant of certiorari by aligning his patents with mainstream patents of others (*see, e.g.*, Pet. 19) fails because his patents are far outside the mainstream. Classen asserts that there are 1,349 U.S. patents claiming "immunizing" (Pet. 19). There is no dispute that immunizing with a new vaccine or for a new indication will generally not raise any issue of patentability under Section 101. Classen has not identified any instance in which another patentee has attempted, as he has, to patent "immunizing" with an existing vaccine according to an existing schedule, and where the only allegedly new step is thinking about a (disputed) collateral benefit of immunizing in that existing way, with no resultant change in physical action or in consequences to the patient.

A. A Patent May Not Claim Nonpatentable Subject Matter.

Section 101 of the patent law delineates the scope of patentable subject matter:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

35 U.S.C. § 101.

Although that scope is broad, it is not unbounded. "Excluded from such patent protection," are "laws of nature, natural phenomena, and abstract ideas." *Diamond v. Diehr*, 450 U.S. 175, 185, 187 (1981); *accord, e.g., Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980); *Parker v. Flook*, 437 U.S. 584, 589 (1978); *Gottschalk v. Benson*, 409 U.S. 63, 67-68 (1972); *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130 (1948); *Mackay Radio & Tel. Co. v. Radio Corp. of Am.*, 306 U.S. 86, 94 (1939). "[M]anifestations of laws of nature" are "part of the storehouse of knowledge," "free to all men and reserved exclusively to none." *Funk Bros.*, 333 U.S. at 130. A "scientific truth, or the mathematical expression of it, is not a patentable invention . . . ." *Mackay Radio*, 306 U.S. at 94. "Phenomena of nature, though just discovered, mental processes, and abstract intellectual concepts are not patentable, as they are the basic tools of scientific and technological work." *Benson*, 409 U.S. at 67. "[O]ne may not patent an idea." *Id.* at 71.

As well known examples of nonpatentable subject matter: "Einstein could not patent his celebrated law that $E=mc^2$; nor could Newton have patented the law of gravity." *Chakrabarty*, 447 U.S. at 309. Nor could one patent "a novel and useful mathematical formula," *Flook*, 437 U.S. at 585; electromagnetism or steam power, *O'Reilly v. Morse*, 56 U.S. (15 How.) 62 (1854); or "[t]he qualities of . . . bacteria, . . . the heat of the sun, electricity, or the qualities of metals," *Funk Bros.*, 333 U.S. at 130; *see LeRoy v. Tatham*, 55 U.S. (14 How.) 156, 175 (1852).

This Court has also held that a patentee may not avoid this basic precept by dressing up nonpatentable subject matter with a claimed feature that, even if arguably patentable subject matter, is not new. As held in *Flook*, the discovery of a nonpatentable phenomenon "cannot support a patent unless there is some other inventive concept in its application." 437 U.S. at 590. The "notion that post-solution activity, no matter how conventional or obvious in itself, can transform an unpatentable principle into a patentable process exalts form over substance." *Id.* at 594; *see also Diehr*, 450 U.S. at 192 n.14 (inclusion of token postsolution activity does not make a mathematical formula patentable).

Contrary to Classen's assertion, this Court did not hold in *Chakrabarty* that Section 101 allows as patentable subject matter any process of "anything under the sun that is made by man." (Pet. 10). "[T]he phrase 'anything under the sun that is made by man' comes from a committee report that said something different. It said a person may have invented *a machine or a manufacture*, which may include anything under

the sun that is made by man." (A1831-36 at A1835) (emphasis added) (*see* Committee language cited in *Chakrabarty*, 447 U.S. at 309). The 1952 Act in adopting Section 101 did not alter this Court's limitations on patentable subject matter applied in earlier cases such as *Funk Bros.* The legislative history indicates that it was codifying such earlier case law.[6]

Since the 1952 Act, this Court has reiterated and applied the basic precept that discoveries of laws of nature and the like are not entitled to patent protection. *See Benson*, 409 U.S. at 71-72; *Flook*, 437 U.S. at 594-95. The Federal Circuit too has acknowledged and applied this precept to hold that such subject matter is not patentable. *E.g. In re Bonczyk*, 2001 U.S. App. LEXIS 9256 (Fed. Cir. 2001); *In re Grams*, 888 F.2d 835, 841 (Fed. Cir. 1989).

B. Classen's Patents Cover A Nonpatentable Mental Process Involving A Nonpatentable Idea.

As framed by this Court's jurisprudence, patentability turns on whether Classen's method "when considered as a whole, is performing a function which the patent laws were designed to protect," *Diehr*, 450 U.S. at 192, or whether instead his method "in practical effect would be a patent on the [idea] itself." *Benson*,

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[6] In the Congressional Record of the debates and proceedings surrounding the passage of the Patent Act of 1952, Senator Wiley stated that "the bill simply constitutes a restatement of the patent laws of the United States." 98 CONG. REC. 9097 (daily ed. July 3, 1952). Senator Saltonstall asked if the patent act changed the law in any way or merely codified existing patent law. *Id.* at 9323. Senator McCarran answered that it merely codified the present patent laws. *Id.*

409 U.S. at 72. The district court correctly acknowledged this analytical framework. (Pet. 12a-15a).

By itself, the abstract idea that certain schedules for immunization against infectious disease may reduce, or increase, the risk of later chronic diseases relative to other schedules is indisputably not patentable. *See Diehr*, 450 U.S. at 185, 188. ("[L]aws of nature, natural phenomena, and abstract ideas," as well as "fundamental truth[s]" and "scientific truth[s]" are not patentable). "[O]ne may not patent an idea." *Benson*, 409 U.S. at 71.

By the same token, *thinking about* the abstract idea of the benefit of an immunization schedule for risk of chronic disease adds nothing to the idea itself and is likewise not patentable. (Pet. 13a-14a); *see Diehr*, 450 U.S. at 184 ("Transformation and reduction of an article 'to a different state or thing' is the clue to the patentability of a process claim that does not include particular machines.") (quoting *Benson*, 409 U.S. at 70); *Benson*, 409 U.S. at 71 ("[M]ental processes are not patentable."). While immunizing with a vaccine may transform the patient's immune system to be resistant to the specific disease, that is the known purpose of the known vaccine. Thinking about collateral consequences does not affect that transformation.

Both courts below recognized that Classen's "invention" of "thinking about" his idea does not add to the idea itself. The district court expressed its holding in those terms (the patents describe "little more than an inquiry") (Pet. 14a), while the Federal Circuit couched its decision in the verbiage of

Diehr (incorporated in *Bilski*) on that point (Classen's claims do not "transform[ ] a particular article into a different state or thing"). (Pet. 3a).

Classen's argument is fundamentally flawed in ignoring that appending the physical step of "immunizing" with a schedule "chosen" during Classen's claimed mental process, without more, cannot transform the nonpatentable mental process into a patentable one, because undisputedly nothing is new in that "immunizing" step (p. 7, *supra*; p. 19, *supra*).[7] One cannot patent a thought process or abstract idea merely by grafting on a non-inventive use. *See Diehr*, 450 U.S. at 192 n.14; *Flook*, 437 U.S. at 590, 594; *Funk Bros.*, 333 U.S. at 131-32. A nonpatentable phenomenon "cannot support a patent unless there is some other inventive concept in its application." *Flook*, 437 U.S. at 594. As this Court held in *Flook*:

> The notion that post-solution activity, no matter how conventional or obvious in itself, can transform an unpatentable principle into a patentable process exalts form over substance. A competent draftsman could attach some form of post-solution activity to almost any mathematical formula; the

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[7] Classen cites *Chakrabarty* for the proposition that because "vaccines are man made," methods of screening immunization schedules would not be covered by a law of nature. (Pet. 10). But Classen did not invent any new vaccine or new, physical way of immunizing, and his petition misses the point that an "abstract idea," as well as "thinking about" an idea, is not patentable.

> Pythagorean theorem would not have been patentable, or partially patentable, because a patent application contained a final step indicating that the formula, when solved, could be usefully applied to existing surveying techniques.

437 U.S. at 590.

Classen's petition cites at some length to certain federal laws relating to medical activity. But nothing in those laws calls for patenting of all medical activities, regardless of whether the requirements of Section 101 (or other sections of the patent code) have been met.

C. Alternative Grounds Support the Judgment.

Even if the Court were to decide to give further consideration to the issue of whether Classen's "invention" is patentable, and even if in so doing, the patents were held to cover patentable subject matter, the judgment of invalidity would still stand on the ground that, as Merck argued below, Classen did not invent anything new.

Classen did not invent the physical steps of any of the patents. Immunizing with hepatitis B vaccine according to an early schedule was published and practiced well prior to August 12, 1992. (p. 7, *supra*). Nor did Classen invent a new research method or new physical steps for "determining" a vaccine immunization schedule by "immunizing" and "comparing." Administering a vaccine to a treatment

group and a control group and then comparing results was far from inventive at the time of Classen's alleged invention. (A1498-502; A1594-600; A1602-06). Moreover, choosing one method of treatment over another based on demonstrated safety differences is nothing more than what has been routine practice of pediatricians (and other health professionals) since long before Classen.

But even if Classen had "discovered" an additional reason (i.e. decreased risk of later chronic disease) for believing an existing immunization schedule using an existing vaccine to be beneficial, Classen's patents could not survive on the basis of his having recognized such (alleged) benefit of the prior art. It is not invention to perceive inherent qualities others failed to detect. *Gen. Elec. Co. v. Jewel Incandescent Lamp Co.*, 326 U.S. 242, 248-49 (1945) ("It is not invention to perceive that the product which others had discovered had qualities they failed to detect."); *Funk Bros.*, 333 U.S. 127; *In re Cruciferous Sprouts Patent Litig.*, 301 F.3d 1343 (Fed. Cir. 2002).

CONCLUSION

For the foregoing reasons, Classen's Petition should be denied.

Respectfully submitted,

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OPPOSITION BRIEF

Supreme Court, U.S.
FILED
OCT 22 2008
OFFICE OF THE CLERK

No. 08-1509

IN THE

Supreme Court of the United States

CLASSEN IMMUNOTHERAPIES, INC.,
Petitioner,

v.

BIOGEN IDEC, GLAXOSMITHKLINE,
AND MERCK & CO., INC.,
Respondents.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

BRIEF IN OPPOSITION FOR RESPONDENT BIOGEN IDEC

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RULE 29.6 CORPORATE DISCLOSURE STATEMENT

Biogen Idec Inc. is a publicly held corporation. It has no parent corporation, and no publicly held company owns 10% or more of Biogen Idec's stock.

TABLE OF AUTHORITIES

CASES

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STATUTES AND RULES

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STATEMENT OF THE CASE

1. Petitioner Classen Immunotherapies, Inc. ("Classen"), is the holder of three patents, each claiming a method of evaluating immunization schedules based on knowledge of a certain "phenomenon" Classen's founder believed he had discovered—that immunizing children on certain schedules allegedly can decrease their risk of developing diabetes or other autoimmune disorders. Pet. 3, 6. Classen alleged that another scientist, Dr. Frank DeStefano, conducted a study that tried to verify this phenomenon by evaluating the correlation between vaccination schedules and the incidence of certain disorders ("DeStefano Study"). Pet. App. 19a.

Classen sued respondents Biogen Idec Inc. ("Biogen"), GlaxoSmithKline ("GSK"), and Merck & Co., Inc. ("Merck") for patent infringement, alleging that they participated in, facilitated, and/or otherwise acted with knowledge of the DeStefano Study. *Classen Immunotherapies, Inc.* v. *Biogen IDEC*, 381 F. Supp. 2d 452, 455 (D. Md. 2005). According to Classen, in order to infringe, respondents need only have assessed the risk of the disorders while being aware of the possible existence of the vaccination-schedule phenomenon he claims to have discovered, even if that assessment does not lead to any change in protocol. Pet. C.A. Br. 41; *see id.* at 7. In this view, merely knowing about the DeStefano Study, regardless of whether the study's result was positive or negative, and deciding to continue an existing vaccination schedule apparently would constitute infringement. *Id.* at 7, 41.

2. The district court (D. Md., Quarles, J.) entered judgment for respondent Biogen in two steps. First, in July 2005, the court granted Biogen's motion to dismiss

three of Classen's claims based on the exemption in 35 U.S.C. § 271(e)(1). This provision permits the use of patented inventions "for uses reasonably related to the development and submission of information" to the FDA. 35 U.S.C. § 271(e)(1). The district court read Classen's complaint to allege Biogen's "participation in [the DeStefano] study," which the court considered to be activity "reasonably related to the development and submission of information required" to be submitted to the FDA. *Classen Immunotherapies, Inc.* v. *Biogen IDEC*, 381 F. Supp. 2d at 456.

Next, in December 2005, the district court granted both Classen's motion for voluntary dismissal (with prejudice) of its sole remaining claim against Biogen and Biogen's motion for dismissal of its counterclaim for invalidity of one of the patents. Pet. App. 17a-18a. At this point, there were no longer any outstanding claims or counterclaims involving Biogen.

Also in December 2005, the district court granted Merck's motion for summary judgment of noninfringement, concluding that there was no "evidence linking Merck" to the DeStefano Study or "to any other study" relating to Classen's supposed discovery. Pet. App. 20a. In August 2006, the district court further granted summary judgment on Merck's counterclaim for invalidity based on 35 U.S.C. § 101. Relying on this Court's decisions in *Diamond* v. *Diehr*, 450 U.S. 175 (1981), and *Diamond* v. *Chakrabarty*, 447 U.S. 303 (1980), the court held that the Classen patents were "an indirect attempt to patent the idea that there is a relationship between vaccine schedules and chronic immune mediated disorders." Pet. App. 14a-15a.

3. The court of appeals affirmed the district court based on invalidity in a non-precedential disposition.

Pet. App. 1a-3a. On February 9, 2009, the court of appeals denied Classen's petition for rehearing en banc, without dissent.

REASONS FOR DENYING THE PETITION

Petitioner presents the question of whether its patents are valid in light of 35 U.S.C. § 101. Biogen respectfully suggests that the petition is suited for immediate denial.[1] Although petitioner asks the Court to hold the petition until the Court has decided *Bilski* v. *Doll*, No. 08-964, *cert. granted*, 129 S. Ct. 2735 (June 1, 2009) (Pet. 21), *Bilski* should have no bearing on the dismissal of the claims against Biogen. Biogen won dismissal based on noninfringement, not invalidity. Pet. App. 18a. In the absence of a pending development that could affect the outcome of the case, denial of the petition is appropriate. *See Lawrence* v. *Chater*, 516 U.S. 163, 167 (1996).

First, the district court's judgment for Biogen rested entirely on Biogen's § 271(e)(1) defense to infringement. The court concluded that the accused activity, relating to the DeStefano Study, was reasonably related to the development of data to submit to the FDA. Assuming that the Court declines to disturb the § 271(e)(1) dismissal,[2] the outcome of *Bilski* should not affect Biogen's liability.

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[1] Biogen joins in the arguments of GSK and Merck in opposition to the petition.

[2] Petitioner suggests as an afterthought that the Court might "desire[] to address the issue" (Pet. 23), but petitioner does not set forth any actual question presented on the issue. *See* S. Ct. R. 14(1)(a) ("Only the questions set out in the petition, or fairly included therein, will be considered by the Court."). Regardless,

Second, Biogen has the same defense to petitioner's claim of infringement that Merck prevailed upon. The district court granted Merck summary judgment of noninfringement because petitioner had "offered no evidence linking Merck" to the DeStefano Study or "any other study or evaluation" of the phenomenon petitioner believes it discovered. Pet. App. 20a. Petitioner does not seek this Court's review of that decision. *See* Pet. i (Questions Presented). The district court's reasoning, left uncontested, would apply equally to Biogen, whose licensee, GSK, was not involved in the DeStefano Study. GSK Opp. 3. The validity of petitioner's patents under § 101 is irrelevant to this determination.

Finally, even as to § 101, the petition does not raise an important question or one related to *Bilski*. Whereas *Bilski* presents the question of what processes are patentable under § 101, petitioner's patents claim a state of mind, rather than a process. Petitioner itself has characterized the patent as covering general thoughts: "The act of considering the data from the DeStefano paper prior to immunizing . . . would be an act of infringement[.]" Pet. C.A. Br. 46. Petitioner has

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there is no important question of federal law with respect to § 271(e)(1). The Federal Circuit's order has no precedential value, Fed. Cir. R. 32.1(d), and petitioner has expressed no disagreement with the precedential opinion on § 271(e)(1) that the Federal Circuit issued about the same time, *Proveris Scientific Corp.* v. *Innovasystems, Inc.*, 536 F.3d 1256 (Fed. Cir. 2008). Petitioner's argument appears to be that the result in this case was inconsistent with *Proveris* because petitioner patented a research tool, but petitioner has repeatedly said that, at least in the mode of infringement it accuses here, "the patent covers a routine therapeutic method of use," not a "research tool" (Pet. C.A. Br. 7-8).

repeatedly asserted that its patents cover thinking about, or "choosing," as petitioner would have it (Pet. 11), a vaccination schedule while having knowledge of Classen's ideas, even if one's choice is to retain a pre-existing schedule (Pet. C.A. Br. 41). In light of petitioner's position, the district court was correct to observe that the patents had claimed not "a specific technique" but "a general inquiry" into vaccine schedules (Pet. App. 14a). As an idea for an inquiry, petitioner's "invention" is unpatentable regardless of the outcome of *Bilski*.

CONCLUSION

The petition does not present an important question of federal law, and it does not present a question similar to any the Court is currently considering. Accordingly, the petition for a writ of certiorari should be denied.

Respectfully submitted.

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OCTOBER 2009

SUPPLEMENTAL BRIEF

No.08-1509

Supreme Court, U.S.
FILED
OCT 2 3 2009
OFFICE OF THE CLERK

In The

Supreme Court of the United States

CLASSEN IMMUNOTHERAPIES, INC,
PETITIONER

v.

BIOGEN IDEC, GLAXOSMITHKLINE, AND
MERCK & CO., INC,
RESPONDENTS

SUPPLEMENTAL BRIEF BY PETITIONER ON PETITION FOR WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

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Prometheus v. Mayo Clinic (CAFC 2008-1413) decided Sept. 16, 2009 ..... 1, 10, 11, 12, 13

CORPORATE DISCLOSURE STATEMENT

Petitioner, Classen Immunotherapies, is a privately owned subchapter S corporation formed in the State of Maryland, and is not associated with any public corporations and has filed a corporate disclosure statement with its original petition for cert which remains accurate.

ARGUMENT

Petitioner, Classen, submits this supplemental brief to bring to the Court's attention a recent decision, Prometheus Laboratories, Inc., v. Mayo Collaborative Services, CAFC 2008-1403 (Decided September 16, 2009), from a different panel at the Court of Appeals for the Federal Circuit, which is in direct conflict with the decision rendered by the Court of Appeals for the Federal Circuit in this matter.

Classen v. Biogen (CAFC 2006-1634, 1649) was decided on December 19, 2008. The *Classen* decision held that methods of medical treatment do not qualify as statutory subject matter under 35 U.S.C. §101.

Prometheus v. Mayo Clinic (CAFC 2008-1413) was decided on September 16, 2009. The *Prometheus* decision held that methods of medical treatment do qualify as statutory subject matter under 35 U.S.C. §101.

In these two decisions, *Classen* and *Prometheus*, different three judge panels of the Court of Appeals for the Federal Circuit considered almost identical method of treatment claims and reached opposite conclusions when applying *Bilski*, CAFC 2007-1130 (Decided October 30, 2008), which is set for oral argument at the United States Supreme Court on November 9, 2009.

The Classen and Prometheus patents are medical methods-of-treatment patents. In both cases, the patents teach new methods of treatment using existing drugs. The claims follow the general formula

of: (i) administration of a drug (physical transformation); (ii) gather and analyze data according to an inventive method and (iii) treat according to the inventive method (physical transformation) based upon an inventive analysis of the collected data.

The claims at issue in *Classen* and *Prometheus* are set forth below. The *Classen* and *Prometheus* decisions are appended hereto.

CHART I	
Classen '739	Prometheus '623
Claim 1 of the '739 Patent:	Claim 1 of the '623 patent is representative of the independent claims asserted by Prometheus in this case: (FedCir)
1. A method of immunizing a mammalian subject which comprises:	1. A method of optimizing therapeutic efficacy for treatment of an immunemediated gastrointestinal disorder, comprising:

(I) screening a plurality of immunization schedules, by (a) identifying a first group of mammals and at least a second group of mammals, said mammals being of the same species, the first group of mammals having been immunized with one or more doses of one or more infectious disease-causing organism-associated immunogens according to a first screened immunization schedule, and the second group of mammals having been immunized with one or more doses of one or more infectious disease-causing organism-associated immunogens according to a second screened immunization schedule, each group of mammals having been immunized according to a different immunization schedule, and	(a) administering a drug providing 6-thioguanine to a subject having said immune-mediated gastrointestinal disorder; and

(b) comparing the effectiveness of said first and second screened immunization schedules in protecting against or inducing a chronic immune-mediated disorder in said first and second groups, as a result of which one of said screened immunization schedules may be identified as a lower risk screened immunization schedule and the other of said screened schedules as a higher risk screened immunization schedule with regard to the risk of developing said chronic immune mediated disorder(s),	(b) determining the level of 6-thioguanine in said subject having saidimmune-mediated gastrointestinal disorder, wherein the level of 6-thioguanine less than about 230 pmol per $8x10^8$ red blood cells indicates a need to increase the amount of said drug subsequently administered to said subject and wherein the level of 6-thioguanine greater than about 400 pmol per $8x10^8$ red blood cells indicates a need to decrease the amount of said drug subsequently administered to said subject.

(II) immunizing said subject according to a subject immunization schedule, according to which at least one of said infectious disease-causing organism-associated immunogens of said lower risk schedule is administered in accordance with said lower risk screened immunization schedule, which administration is associated with a lower risk of development of said chronic immune-mediated disorder(s) than when said immunogen was administered according to said higher risk screened immunization schedule.	

CHART II - Statutory Subject Matter		
Classen '739	35 USC §101	Prometheus '623
Claim 1 of the '739 Patent:	Statutory Subject Matter	"Claim 1 of the '623 patent is representative of the independent claims asserted by Prometheus in this case:" (FedCir)
1. A method of immunizing a mammalian subject which comprises:	Method of treatment comprising:	1. A method of optimizing therapeutic efficacy for treatment of an immunemediatd gastrointestinal disorder, comprising:

(I) screening a plurality of immunization schedules, by (a) identifying a first group of mammals and at least a second group of mammals, said mammals being of the same species, the first group of mammals having been immunized with one or more doses of one or more infectious disease-causing organism-associated immunogens according to a first screened immunization schedule, and the second group of mammals having been immunized with one or more doses of one or more infectious disease-causing organism-associated immunogens according to a second screened	STEP ONE administer a drug (physical transformation)	(a) administering a drug providing 6-thioguanine to a subject having said immune-mediated gastrointestinal disorder; and (physical transformation step for data gathering)

(b) comparing the effectiveness of said first and second screened immunization schedules in protecting against or inducing a chronic immune-mediated disorder in said first and second groups, as a result of which one of said screened immunization schedules may be identified as a lower risk screened immunization schedule and the other of said screened schedules as a higher risk screened immunization schedule with regard to the risk of developing said chronic immune mediated disorder(s),	STEP TWO gather and analyze data according to inventive method	(b) determining the level of 6-thioguanine in said subject having said immune-mediated gastrointestinal disorder, wherein the level of 6-thioguanine less than about 230 pmol per $8x10^8$ red blood cells indicates a need to increase the amount of said drug subsequently administered to said subject and wherein the level of 6-thioguanine greater than about 400 pmol per $8x10^8$ red blood cells

(II) immunizing said subject according to a subject immunization schedule, according to which at least one of said infectious disease-causing organism-associated immunogens of said lower risk schedule is administered in accordance with said lower risk screened immunization schedule, which administration is associated with a lower risk of development of said chronic immune-mediated disorder(s) than when said immunogen was administered according to said higher risk screened immunization schedule. (physical transformation step is repeated for treatment)	STEP THREE treat according to inventive method (physical transformation)	(physical transformation step is not repeated for treatment in Prometheus)

The District Court, when analyzing the Classen patents, found that the patents included an immunization step. See for example the District Court Decision (Dkt #151) Page 12:

> "Both the 139 and 739 patents claim "a method of immunizing a mammalian subject" which requires: 1) comparing the incidence of immune mediated disorders in treatment groups with different vaccination schedules; and 2) immunizing patients on a schedule identified as low risk. 139 Patent, Claim 1; 739 Patent, Claim 1."

According to the *Prometheus* decision of the Court of Appeals of the Federal Circuit, this immunization step would cause the method of treatment claims of the Classen patents to "fall squarely within the realm of patentable subject matter." See Prometheus at page 14: (emphasis added)

> We conclude that the methods of treatment claimed in the patents in suit squarely fall within the realm of patentable subject matter because they "transform an article into a different state or thing," and this transformation is "central to the purpose of the claimed process." See Bilski, 545 F.3d at 962. The transformation is of the human body ***following administration of a drug*** and the various chemical and physical changes of the drug's metabolites that enable their concentrations to be

> determined. Because the claimed methods meet the transformation prong under Bilski, we do not consider whether they also meet the machine prong.

and at page 15:

> Contrary to the district court, we do not view the disputed claims as merely claiming natural correlations and data-gathering steps. The asserted claims are in effect claims to methods of treatment, which are always transformative ***when a defined group of drugs is administered to the body*** to ameliorate the effects of an undesired condition. More specifically, Prometheus here claimed methods for optimizing efficacy and reducing toxicity of treatment regimes for gastrointestinal and non-gastrointestinal autoimmune diseases that utilize drugs providing 6-TG by administering a drug to a subject. ***The invention's purpose to treat the human body is made clear in the specification and the preambles of the asserted claims.***

However, the panel which decided *Classen* reached the opposite conclusion on the same set of facts, when applying *Bilski*:

> In light of our decision in In re Bilski, 545 F.3d 943 (Fed. Cir. 2008) (en banc), we affirm the district court's grant of

> summary judgment that these claims are invalid under 35 U.S.C. § 101. Dr. Classen's claims are neither "tied to a particular machine or apparatus" nor do they "transform[] a particular article into a different state or thing." Bilski, 545 F.3d at 954.

While the *Classen* panel did not discuss nor detail the reasoning behind its denial of statutory subject matter for method of treatment claims, the *Prometheus* panel discussed the subject matter underlying its reasoning, which applies equally to the Classen patent, when comparing the claims of Classen to the discussion of the claims of Prometheus:

Prometheus decision at page 15:

> See '623 patent col.2 ll.16-19 ("The present invention provides a method of optimizing therapeutic efficacy of 6-mercaptopurine drug treatment of an immune-mediated gastrointestinal disorder."); see, e.g., id. claim 1 ("A method of optimizing therapeutic efficacy for treatment of an immune-mediated gastrointestinal disorder, comprising . . ."); id. claim 7 ("A method of reducing toxicity associated with treatment of an immune-mediated gastrointestinal disorder, comprising . . ."); id. claim 22 ("A method of optimizing therapeutic efficacy of treatment of a non-IBD autoimmune disease, comprising . . .").

Classen Patent, Column 1:

> The present invention involves the fields of immunology and medicine, and more particularly relates to immunization methods, and compositions used therewith, for immunizing young mammals, such as human infants and children, against at least one chronic immune mediated disorder, and, preferably, also against at least one infectious disease.

Claims:

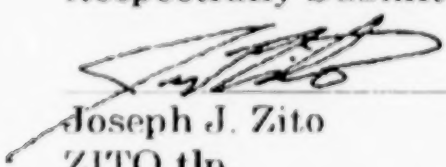
> 1. A method of immunizing a mammalian subject which comprises:
> 71. A method of immunizing a mammalian subject which comprises: . . .
> 96. A method of protecting a mammalian subject, by immunization, against at least one infectious disease while reducing the risk of said subject thereby developing a chronic immune mediated disorder, which comprises: . . .
> 99. The method of claim 98 where one of said chronic immune-mediated disorders is diabetes, . . .
> 104. A method of protecting a mammalian subject, by immunization, against at least one infectious disease while reducing the risk of said subject thereby developing a chronic immune mediated disorder, which comprises: immunizing said subject according to a subject immunization schedule, according to which one or more immunogens is administered to the

subject, each immunogen being administered on one or more dates according to such schedule, where it has previously been determined that the timing of first administration of at least one of said immunogens influences the risk of said subject thereby developing said disorder, and where the first administration of at least one risk-influencing immunogen according to said schedule is timed so as to reduce the risk of said subject thereby developing said disorder, relative to the risk if said first administration had been at some later date.

CONCLUSION

The reasoning of the *Prometheus* decision, which petitioner believes is correct, renders the claims of the Classen patents at issue valid under 35 U.S.C. §101, as they are clearly directed to statutory subject matter. Petitioner therefore repeats its request that the decision of the Court of Appeals for the Federal Circuit be reversed or that this matter be remanded for further consideration in light of *Prometheus* and/or this Court's decision on *Bilski* after oral hearing currently set for November 9, 2009.

Respectfully Submitted



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APPENDIX

Note: This disposition is nonprecedential.

United States Court of Appeals for the Federal Circuit

2006-1634, -1649

CLASSEN IMMUNOTHERAPIES, INC.,
Plaintiff-Appellant,
v.
BIOGEN IDEC,
Defendant-Appellee,
and
GLAXOSMITHKLINE,
Defendant-Appellee,
and
MERCK & CO., INC.,
Defendant-Cross Appellant,
and
CHIRON CORPORATION, KAISER-PERMANENTE, INC., KAISER PERMANENTE VENTURES, KAISER PERMANENTE INTERNATIONAL, KAISER PERMANENTE INSURANCE COMPANY, THE PERMANENTE FEDERATION, LLC, THE PERMANENTE COMPANY, LLC, THE PERMANENTE FOUNDATION, THE PERMANENTE MEDICAL GROUP, INC., KAISER FOUNDATION HOSPITALS, KAISER FOUNDATION ADDED CHOICE HEALTH PLAN, INC., and KAISER FOUNDATION HEALTH PLAN INC.,
Defendants.

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Mary B. Graham, Morris, Nichols, Arsht & Tunnell, LLP, of Wilmington, Delaware, argued for defendant-cross appellant. With her on the brief was James W. Parrett, Jr. Of counsel on the brief were Robert L. Baechtold, Fitzpatrick, Cella, Harper & Scinto, of New York, New York; and Edward W. Murray and Mary J. Morry, Merck & Co., Inc., of Rahway, New Jersey.

Appealed from: United States District Court for the District of Maryland in Case No. 04-CV-2607, Judge William D. Quarles, Jr.

DECIDED: December 19, 2008

Before NEWMAN and MOORE, Circuit Judges, and FARNAN, District Judge. *

MOORE, Circuit Judge.

In light of our decision in In re Bilski, 545 F.3d 943 (Fed. Cir. 2008) (en banc), we affirm the district court's grant of summary judgment that these claims are invalid under 35 U.S.C. § 101. Dr. Classen's claims are neither "tied to a particular machine or apparatus" nor do they "transform[] a particular article into a different state or thing." Bilski, 545 F.3d at 954. Therefore we affirm.

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* Hon. Joseph J. Farnan, Jr., United States District Court for the District of Delaware, sitting by designation.

United States Court of Appeals for the Federal Circuit

2008-1403

PROMETHEUS LABORATORIES, INC.,

Plaintiff-Appellant,

v.

MAYO COLLABORATIVE SERVICES (doing business as Mayo Medical Laboratories) and MAYO CLINIC ROCHESTER,

Defendants-Appellees.

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Appeal from the United States District Court for the Southern District of California
in Case No. 04-CV-1200, Judge John A. Houston.

DECIDED: September 16, 2009

Before MICHEL, Chief Judge, LOURIE, Circuit Judge, and CLARK, District Judge.*
LOURIE, Circuit Judge.

Prometheus Laboratories, Inc. ("Prometheus") appeals from the final judgment of the United States District Court for the Southern District of California granting summary judgment of invalidity of U.S. Patents 6,355,623 ("the '623 patent") and 6,680,302 ("the '302 patent") under 35 U.S.C. § 101. Prometheus Labs., Inc. v. Mayo Collaborative Servs., No. 04-CV-1200, 2008 WL 878910 (S.D. Cal. Mar. 28, 2008) ("Invalidity Opinion"). Because the district court erred as a matter of law in finding the asserted claims to be drawn to non-statutory subject matter, we reverse.

BACKGROUND

Prometheus is the sole and exclusive licensee of the '623 patent and the '302 patent. The patents claim methods for calibrating the proper dosage of thiopurine drugs, which are used for treating both gastrointestinal and non-gastrointestinal

* Honorable Ron Clark, District Judge, United States District Court for the Eastern District of Texas, sitting by designation.

autoimmune diseases. These drugs include 6-mercaptopurine ("6-MP") and azathiopurine ("AZA"), a pro-drug that upon administration to a patient converts to 6-MP, which are used to treat inflammatory bowel diseases ("IBD") such as Crohn's disease and ulcerative colitis. 6-MP is broken down by the body into various 6-MP metabolites, including 6-methyl-mercaptopurine ("6-MMP") and 6-thioguanine ("6-TG") and their nucleotides.[1] The patents involve measurements of these two metabolites. Drugs that deliver 6-TG are widely used for their cytotoxic and immunosuppressive properties.

Although drugs such as 6-MP and AZA have been used for years to treat autoimmune diseases, non-responsiveness and drug toxicity may complicate treatment in some patients. To that end, the patents claim methods that seek to optimize therapeutic efficacy while minimizing toxic side effects. As written, the methods typically include two separately lettered steps: (a) "administering" a drug that provides 6-TG to a subject and (b) "determining" the levels of the drug's metabolites, 6-TG and/or 6-MMP, in the subject. See, e.g., '623 patent claim 1. The measured metabolite levels are then compared to pre-determined metabolite levels, "wherein" the measured metabolite levels "indicate a need" to increase or decrease the level of drug to be administered so as to minimize toxicity and maximize efficacy of treatment. See, e.g., id. In particular, according to the patents, a 6-TG level greater than about 400 picomole ("pmol") per 800 million red blood cells or a 6-MMP level greater than about 7000 pmol per 800 million red blood cells indicates that a downward adjustment in drug dosage may be required in order to avoid toxic side effects. See id. col.20 ll.22, 54. Conversely, according to the patents, a 6-TG level of less than about 230 pmol per 800 million red blood cells indicates a need to increase the dosage

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[1] For the purposes of this opinion, "6-TG" encompasses 6-thioguanine nucleotides.

to ensure therapeutic efficacy. See id. col.20 ll.18-19.

Claim 1 of the '623 patent is representative of the independent claims asserted by Prometheus in this case:

A method of optimizing therapeutic efficacy for treatment of an immune-mediated gastrointestinal disorder, comprising:

(a) administering a drug providing 6-thioguanine to a subject having said immune-mediated gastrointestinal disorder; and

(b) determining the level of 6-thioguanine in said subject having said immune-mediated gastrointestinal disorder,

wherein the level of 6-thioguanine less than about 230 pmol per 8x108 red blood cells indicates a need to increase the amount of said drug subsequently administered to said subject and

wherein the level of 6-thioguanine greater than about 400 pmol per 8x108 red blood cells indicates a need to decrease the amount of said drug subsequently administered to said subject.

Claim 1 of the '302 patent is substantially the same, with the inclusion of determining 6-MMP levels in addition to 6-TG.

Prometheus marketed a PROMETHEUS Thiopurine Metabolites test (formerly known as the PRO-PredictRx® Metabolites test) that used the technology covered by the patents in suit. Mayo Collaborative Services and Mayo Clinic Rochester (together, "Mayo") formerly purchased and used Prometheus's test, but in 2004, Mayo announced that it intended to begin using internally at its clinics and selling to other hospitals its own test. Mayo's test measured the same metabolites as Prometheus's test, but Mayo's test used different levels to determine toxicity of 6-TG and 6-MMP.

On June 15, 2004, Prometheus sued Mayo for infringement of the patents. Prometheus asserted independent claims 1, 7, 22, 25, and 46 of the '623 patent and independent claim 1 of the '302 patent. Most of these claims cover a

"method for optimizing therapeutic efficacy" and/or "reducing toxicity" in patients taking a drug such as AZA or 6-MP in the treatment of an immune-mediated gastrointestinal disease. See '623 patent claims 1, 7, 25, & 46; '302 patent claim 1. One independent claim was for treatment of a non-IBD autoimmune disease. See '623 patent claim 22. Prometheus also asserted several dependent claims that require either that the measurement of the metabolites is done using high pressure liquid chromatography, see '623 patent claims 6, 14, 24, 30, and 53, or that the thiopurine drug used is one of four specified drugs, see '623 patent claims 32, 33, 35, and 36. Mayo rescinded its announcement shortly after the lawsuit was filed and still has not launched its test.

On November 22, 2005, the district court held on cross-motions for summary judgment that Mayo's test literally infringed claim 7 of the '623 patent. Prometheus Labs., Inc. v. Mayo Collaborative Servs., No. 04-CV-1200, slip op. at 23 (S.D. Cal. Nov. 22, 2005) (Dkt. No. 227). In its opinion, the court construed "indicates a need" to mean "a warning that an adjustment in dosage may be required." Id. at 18. This construction did not require doctors to adjust drug dosage if the metabolite level reached the specified levels; rather, the court found the wherein phrases to mean "that when the identified metabolites reach the specified level, the doctor is warned or notified that a dosage adjustment may be required, if the doctor believes that is the proper procedure." Id. at 17-18.

On January 29, 2007, Mayo filed a motion for summary judgment of invalidity, arguing that the patents in suit are invalid because they claim unpatentable subject matter under 35 U.S.C. § 101. Specifically, Mayo contended that the patents impermissibly claim natural phenomena—the correlations between, on the one hand, thiopurine drug metabolite levels and, on the other hand, efficacy and toxicity—and that the claims wholly preempt use of the natural phenomena.

On March 28, 2008, the district court granted Mayo's motion for summary judgment of invalidity under § 101. First,

the court found that the patents claimed the correlations between certain thiopurine drug metabolite levels and therapeutic efficacy and toxicity. The court reasoned that, as construed in the November 2005 summary judgment order, the claims have three steps: (1) administer the drug to a subject; (2) determine metabolite levels; and (3) be warned that an adjustment in dosage may be required. The court stated that the fact that inventors framed the claims as treatment methods does not render the claims patentable. Rather, the court found that the "'administering' and 'determining' steps are merely necessary data-gathering steps for any use of the correlations" and that "as construed, the final step—the 'warning' step (i.e. the 'wherein' clause)—is only a mental step." Invalidity Opinion, 2008 WL 878910, at *6. The court noted that the warning step does not require any actual change in dosage and that "it is the metabolite levels themselves that 'warn' the doctor that an adjustment in dosage may be required." Id. With this understanding of the claims, the court concluded that the claims recited the correlations between particular concentrations of 6-TG and 6-MMP and therapeutic efficacy or toxicity in patients taking AZA drugs.

Second, the district court found that those correlations were natural phenomena and not patentable inventions because the correlations resulted from a natural body process. The court stated that the inventors did not "invent" the claimed correlation; rather, "6-TG and 6-MMP are products of the natural metabolizing of thiopurine drugs, and the inventors merely observed the relationship between these naturally produced metabolites and therapeutic efficacy and toxicity." Invalidity Opinion, 2008 WL 878910, at *7. Finally, the court determined that "[b]ecause the claims cover the correlations themselves, it follows that the claims 'wholly pre-empt' the correlations." Id. at *11. Thus, the court concluded that there was no genuine issue of material fact to be resolved as to whether the patents in suit were directed to statutory subject matter and found by clear and convincing evidence that the

claims were invalid under § 101.

On May 16, 2008, the district court entered final judgment, disposing of all the parties' claims and counterclaims. On May 30, 2008, Prometheus timely appealed the district court's grant of summary judgment of invalidity under § 101. We have jurisdiction pursuant to 28 U.S.C. § 1295(a)(1).

DISCUSSION

A. Standard of Review

We review the district court's grant of summary judgment de novo. AT&T Corp. v. Excel Commc'ns, 172 F.3d 1352, 1355 (Fed. Cir. 1999). Summary judgment is appropriate if there are no genuine issues of material fact and the moving party is entitled to judgment as a matter of law. Id.; Fed. R. Civ. P. 56(c). Whether a patent claim is directed to statutory subject matter is a question of law that we review de novo. AT&T, 172 F.3d at 1355.

B. Section 101

The issue before us is whether the claims meet the requirements of § 101, so we begin with the text of the statute. Section 101 provides that:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent thereof, subject to the conditions and requirements of this title.

35 U.S.C. § 101. According to § 100(b), "[t]he term 'process' means process, art, or method, and includes a new use of a known process, machine, manufacture, composition of matter, or materials." 35 U.S.C. § 100(b). But, as noted in In re Bilski, this definition of process is "unhelpful" because the definition itself uses the term "process." 545 F.3d 943, 951 n.3 (Fed. Cir. 2008) (en banc), cert. granted, 129 S. Ct. 2735 (June 1, 2009). Thus, we turn to the case law to guide our understanding of what constitutes statutory subject matter under § 101.

The Supreme Court has construed § 101 broadly, noting that Congress intended statutory subject matter to "include anything under the sun that is made by man." Diamond v. Chakrabarty, 447 U.S. 303, 309 (1980). It is well-established, however, that this sweeping statement does not indicate that § 101 is unlimited and embraces every discovery:

> [A] new mineral discovered in the earth or a new plant found in the wild is not patentable subject matter. Likewise, Einstein could not patent his celebrated law that E=mc2; nor could Newton have patented the law of gravity. Such discoveries are "manifestations of . . . nature, free to all men and reserved exclusively to none."

Id. (quoting Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 130 (1948)). More specifically, the Court has held that a claim to a process is not patent-eligible if it claims "laws of nature, natural phenomena, and abstract ideas." Diamond v. Diehr, 450 U.S. 175, 185 (1981); see also Gottschalk v. Benson, 409 U.S. 63, 67 (1972) ("Phenomena of nature, though just discovered, mental processes, and abstract intellectual concepts are not patentable, as they are the basic tools of scientific and technological work.").

At the same time, it has also been established that "while a claim drawn to a fundamental principle"—i.e., a law of nature, natural phenomenon, or abstract idea—"is unpatentable, 'an application of a law of nature or mathematical formula to a known structure or process may well be deserving of patent protection.'" Bilski, 545 F.3d at 953 (quoting Diehr, 450 U.S. at 187). The key issue for patentability, then, at least on the present facts, is whether a claim is drawn to a fundamental principle or an application of a fundamental principle. Although this inquiry is hardly straightforward, following the Supreme Court, we articulated in Bilski a "definitive test" for determining whether a process is patent-eligible under § 101: "A claimed process is surely patent-eligible under § 101 if: (1) it is tied to a particular

machine or apparatus, or (2) it transforms a particular article into a different state or thing." Id. The machine-or-transformation test is a "two-branched inquiry," i.e., the patentee "may show that a process claim satisfies § 101 either by showing that his claim is tied to a particular machine, or by showing that his claim transforms an article." Id. at 961.

The machine-or-transformation test has two further aspects: "the use of a specific machine or transformation of an article must impose meaningful limits on the claim's scope to impart patent-eligibility," and "the involvement of the machine or transformation in the claimed process must not merely be insignificant extra-solution activity." Bilski, 545 F.3d at 961-62 (citations omitted). "This transformation must be central to the purpose of the claimed process." Id. at 962. Thus, in most cases, one cannot ground the transformative nature of a process in a step that is "insignificant extra-solution activity" or merely a "data-gathering step." See id. at 963 ("Further, the inherent step of gathering data can also fairly be characterized as insignificant extra-solution activity."). In other words, if steps of a method are included for the purpose of data-gathering rather than being "central" to the purpose of the process, the patentee likely cannot rely on the data-gathering steps to prove that the claimed process is transformative and thus drawn to patentable subject matter. See id. at 963 (stating that mere data-gathering will not, "at least in most cases, . . . constitute a transformation of any article").

The Supreme Court has also made clear that the patent eligibility of a claim as a whole should not be based on whether selected limitations constitute patent-eligible subject matter. See Bilski, 545 F.3d at 958 (citing Diehr, 450 U.S. at 188; Parker v. Flook, 437 U.S. 584, 594 (1978)). As noted in Diehr, the Court has specifically stated that it is "inappropriate to dissect the claims into old and new elements and then to ignore the presence of the old elements in the analysis." 450 U.S. at 188. Moreover, it is improper to consider whether a claimed element or step in a process is novel or nonobvious, since such

considerations are separate requirements set forth in 35 U.S.C. §§ 102 and 103, respectively. Bilski, 545 F.3d at 958 (citing Dichr, 450 U.S. at 188-91). With this understanding of the present state of the law, we now turn to the parties' arguments in the instant action.

C. Analysis

On appeal, Prometheus argues that the claimed processes satisfy § 101 because they meet both prongs of the machine-or-transformation test articulated in Bilski. With respect to the machine prong, Prometheus argues that the patents inextricably rely on numerous machines to process the bodily sample, determine the metabolite levels, and thereby calibrate the proper dose. Prometheus asserts that the district court erred by failing to consider separately the asserted dependent claims, some of which specify measurement through high pressure liquid chromatography, which clearly requires the use of machines. In addition, Prometheus contends that Bilski's use of "machine" in its machine-or-transformation test must be read as shorthand for all patentable subject matter, including compositions of matter. To that end, Prometheus argues that the synthetic drugs used in its treatment methods are compositions of matter, and the claims' central reliance on those drugs is enough to meet the machine-or-transformation test. Alternatively, Prometheus asserts that we should recognize that Bilski does not apply where, as here, the treatment methods use synthetic drugs and thus do not recite or wholly preempt any natural phenomenon.

With respect to the transformation prong, Prometheus points to three "transformations" within its claimed process: (1) the first step of administering a synthetic drug transforms the biochemical makeup of the patient's body for the purpose of treating disease; (2) the second step requires the transformation of a bodily sample to determine the created metabolites' concentration levels; and (3) the metabolite levels are transformed into a warning for a doctor to alter the dosage.

Regarding the first asserted transformation, Prometheus argues that physical transformations, such as the human body's metabolic reaction to drugs, initiated by human actions and artificial chemical compounds, such as the administration of a thiopurine drug into the body, cannot be unpatentable under Bilski simply because they proceed according to natural laws or occur within the human body. Prometheus contends that everything proceeds according to natural laws. Regarding the second asserted transformation, Prometheus argues that all of the several methods available to determine the metabolite levels in a bodily sample require a physical transformation of blood or human tissue in order to extract the metabolite and determine its concentration. Finally, regarding the third asserted transformation, Prometheus posits that the ultimate end of the processes is to transform—and improve—the patient's treatment regime while avoiding deadly side effects by transforming the metabolite levels into a warning regarding dosage.

Prometheus then argues that these machines and transformations are central to the invention's purpose of improving a process of treatment and are not confined to extra-solution activity. Prometheus asserts that the district court erred by parsing the steps of the treatment method rather than looking at the method as a whole, which applies the correlations in concrete physical processes—that Prometheus argues are patentable absent the correlation—to generate useful information. Prometheus contends that adoption of the district court's reasoning would have the effect of eliminating all medical treatment and diagnostic patents, when future medical advances will depend on optimizing treatment based on genetic or other testing.

Mayo responds that the district court properly examined the claims as a whole and correctly determined that they recite the correlations themselves, which are natural phenomena. With respect to the machine prong, Mayo argues that any involvement of machines is insignificant extra-solution

activity. Mayo asserts that the step of determining the metabolite levels via an unspecified machine is merely gathering data that is necessary to correlate information. Mayo argues that Bilski requires the use of a "particular machine or apparatus" and that no particular machine is involved in Prometheus's process. Mayo contends that Prometheus's reliance on the dependent claims reciting the use of high pressure liquid chromatography is misplaced because choosing to limit the claims to one possible method for performing one of the steps is not sufficient to impart patentability over a natural phenomenon.

Similarly, with respect to the transformation prong, Mayo argues that there is no patentable transformation in the claimed processes. First, Mayo asserts that the administering step is merely a data-gathering step. Mayo points out that the asserted claims do not all include the administering step and thus argues that the administration of the drug cannot be central to the claim. Mayo also contends that although the thiopurine drugs used in the claims are synthetic, the body's reaction to them is natural, and the drugs themselves were well known. Second, Mayo argues that the determining step is also data-gathering necessary to make any use of the correlations, and the presence of the physical step of transforming clinical samples does not impart patentability to claims to natural correlations. Third, Mayo argues that there is no transformation of data into a warning because the claims do not require any action to be taken to adjust dosage. Under the claim construction argued by Prometheus and adopted by the district court, the final step is a mental step and thus, Mayo argues, the data undergoes no transformation at all.

Furthermore, Mayo asserts that the district court properly determined not only that the claims were to the correlations themselves but that the claims preempt all practical use of the correlations. Post-Bilski, Mayo argues that Supreme Court precedent invalidating a claim that wholly preempts a natural phenomenon such that the practical effect is a patent on

the phenomenon itself still stands. Mayo contends that because nothing is done with the naturally occurring correlation, the claims cover all implementations resulting from that natural phenomenon and are thus unpatentable. Finally, Mayo argues that invalidating Prometheus's claims will not affect medical treatment methods because infringement of the asserted claims requires no act by a physician at all and no treatment of any disease or condition in a patient. Furthermore, Mayo asserts that upholding the claims under § 101 is dangerous because infringement would occur any time the natural correlation was even considered by a physician.

A number of amici curiae filed helpful briefs on both sides. Those supporting Prometheus argued that the transformation that flows from the use of thiopurine drugs in the patented processes is not "insignificant" post-solution activity but rather a specific and practical application of the correlations in medical treatment. They also argue that the future of personalized medicine will involve knowledge of the physiological or biological significance of biomarkers and how to use them in diagnostic or therapeutic procedures and that patents on those biomarkers should be granted. Those supporting Mayo argue that the district court properly found that the claims impermissibly preempt a natural statistical correlation by asserting exclusive rights over the mere recognition by a treating physician of those correlations. They argue that finding Prometheus's claim to cover patentable subject matter would be granting exclusive rights over mere knowledge of the correlations and would thus interfere with the provision of medical care and with research and quality control in clinical chemistry.

1. The administering and determining steps are transformative

We agree with Prometheus that the asserted claims are drawn to statutory subject matter and thus reverse the district court's grant of Mayo's motion for summary judgment of invalidity. As an initial matter, we note that the only issue

before us is whether the claims meet the requirements of § 101. This appeal does not raise any questions about lack of novelty, obviousness, or overbreadth, since those are separate statutory requirements for patentability under §§ 102, 103, and 112, respectively. See Bilski, 545 F.3d at 958 (citing Diehr, 450 U.S. at 188-91). The proper inquiry under § 101 is whether these methods meet the Supreme Court's machine or transformation test articulated in Benson and Diehr, and applied in Bilski, and, if so, whether the machine or the transformation is central to the purpose of the claims.[2]

We conclude that the methods of treatment claimed in the patents in suit squarely fall within the realm of patentable subject matter because they "transform an article into a different state or thing," and this transformation is "central to the purpose of the claimed process." See Bilski, 545 F.3d at 962. The transformation is of the human body following administration of a drug and the various chemical and physical changes of the drug's metabolites that enable their concentrations to be determined. Because the claimed methods meet the transformation prong under Bilski, we do not consider whether they also meet the machine prong.

Contrary to the district court, we do not view the disputed claims as merely claiming natural correlations and data-gathering steps.[3] The asserted claims are in effect claims

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[2] We note that the district court did not have the benefit of our Bilski decision when deciding the § 101 issue. However, we believe that even prior to Bilski, the asserted claims should have been found to be patentable subject matter under the Supreme Court's decisions in Benson and Diehr and our cases such as In re Grams, 888 F.2d 835 (Fed. Cir. 1989), and In re Abele, 684 F.2d 902 (CCPA 1982).

[3] In reaching its conclusion, the district court relied heavily on the opinion of three justices dissenting from the

to methods of treatment, which are always transformative when a defined group of drugs is administered to the body to ameliorate the effects of an undesired condition. More specifically, Prometheus here claimed methods for optimizing efficacy and reducing toxicity of treatment regimes for gastrointestinal and non-gastrointestinal autoimmune diseases that utilize drugs providing 6-TG by administering a drug to a subject. The invention's purpose to treat the human body is made clear in the specification and the preambles of the asserted claims. See '623 patent col.2 ll.16-19 ("The present invention provides a method of optimizing therapeutic efficacy of 6-mercaptopurine drug treatment of an immune-mediated gastrointestinal disorder."); see, e.g., id. claim 1 ("A method of optimizing therapeutic efficacy for treatment of an immune-mediated gastrointestinal disorder, comprising . . ."); id. claim 7 ("A method of reducing toxicity associated with treatment of an immune-mediated gastrointestinal disorder, comprising . . ."); id. claim 22 ("A method of optimizing therapeutic efficacy of treatment of a non-IBD autoimmune disease, comprising . . .").

When administering a drug such as AZA or 6-MP, the human body necessarily undergoes a transformation. The drugs do not pass through the body untouched without affecting it. In fact, the transformation that occurs, viz., the effect on the body after metabolizing the artificially administered drugs, is the entire purpose of administering these drugs: the drugs are

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dismissal of the grant of certiorari in Laboratory Corp. of America Holdings v. Metabolite Laboratories, Inc., 548 U.S. 124 (2006) (Breyer, J., dissenting). See Invalidity Opinion, 2008 WL 878910, at *8 (discussing the dissent in Laboratory Corp. at length and stating that although the dissent "does not have precedential value, the Court finds Justice Breyer's reasoning persuasive"). That dissent is not controlling law and also involved different claims from the ones at issue here.

administered to provide 6-TG, which is thought to be the drugs' active metabolite in the treatment of disease, to a subject. See '623 patent col.1 ll.49-51. The fact that the change of the administered drug into its metabolites relies on natural processes does not disqualify the administering step from the realm of patentability. As Prometheus points out, quite literally every transformation of physical matter can be described as occurring according to natural processes and natural law. Transformations operate by natural principles. The transformation here, however, is the result of the physical administration of a drug to a subject to transform—i.e., treat—the subject, which is itself not a natural process. "It is virtually self-evident that a process for a chemical or physical transformation of physical objects or substances is patent-eligible subject matter." See Bilski, 545 F.3d at 962. The administering step, therefore, is not merely data-gathering but a significant transformative element of Prometheus's claimed methods of treatment that is "sufficiently definite to confine the patent monopoly within rather definite bounds." Id. (quoting Benson, 409 U.S. at 70).

Mayo is correct that not all of the asserted claims contain the administering step. That omission, which occurs in claims 46 and 53 of the '623 patent, does not diminish the patentability of the claimed methods because the determining step, which is present in each of the asserted claims, is also transformative and central to the claimed methods. Determining the levels of 6-TG or 6-MMP in a subject necessarily involves a transformation, for those levels cannot be determined by mere inspection. Some form of manipulation, such as the high pressure liquid chromatography method specified in several of the asserted dependent claims or other modification of the substances to be measured, is necessary to extract the metabolites from a bodily sample and determine their concentration. As stated by Prometheus's expert, "at the end of the process, the human blood sample is no longer human blood; human tissue is no longer human tissue." Decl. of Dr.

Yves Théorêt ¶ 6, Prometheus Labs., Inc. v. Mayo Collaborative Servs., No. 04-CV-1200 (S.D. Cal. Mar. 29, 2007) (Dkt No. 528-3). That is clearly a transformation. In fact, Mayo does not dispute that determining metabolite levels in the clinical samples taken from patients is transformative, but argues that this transformation is merely a necessary data-gathering step for use of the correlations. Appellees' Br. 37 ("The 'transformation' of the patient's sample is merely a necessary data-gathering step. . . . [T]he presence of the physical step of transforming clinical samples taken from patients does not impart patentability to Prometheus' claims to the natural correlations."). On the contrary, this transformation is central to the purpose of the claims, since the determining step is, like the administering step, a significant part of the claimed method of treatment. Measuring the levels of 6-TG and 6-MMP is what enables possible adjustments to thiopurine drug dosage to be detected for optimizing efficacy or reducing toxicity during a course of treatment. The determining step, by working a chemical and physical transformation on physical substances, likewise sufficiently confines the patent monopoly, as required by Bilski.

2. The administering and determining steps are not merely data-gathering

A further requirement for patent-eligibility is ensuring that the involvement of the transformation in Prometheus's claimed process is "not merely insignificant extra-solution activity." Bilski, 545 F.3d at 962 (citing Flook, 437 U.S. at 590). As made clear from the discussion above, the administering and determining steps are transformative and are central to the claims rather than merely insignificant extra-solution activity.

The crucial error the district court made in reaching the opposite conclusion was failing to recognize that the first two steps of the asserted claims are not merely data-gathering steps. See Invalidity Opinion, 2008 WL 878910, at *6 (finding that

"the 'administering' and 'determining' steps are merely necessary data-gathering steps for any use of the correlations"). While it is true that the administering and determining steps gather useful data, it is also clear that the presence of those two steps in the claimed processes is not "merely" for the purpose of gathering data. Instead, the administering and determining steps are part of a treatment protocol, and they are transformative. As explained above, the administering step provides thiopurine drugs for the purpose of treating disease, and the determining step measures the drugs' metabolite levels for the purpose of assessing the drugs' dosage during the course of treatment.

Given the integral involvement of the administering and determining steps in Prometheus's therapeutic methods, this case is easily distinguishable from prior cases that found asserted method claims to be unpatentable for claiming data-gathering steps and a fundamental principle. Perhaps the case that offers the closest comparison is In re Grams, 888 F.2d 835 (Fed. Cir. 1989), but the asserted claims found unpatentable in that case are readily distinguished from those in the instant action. In Grams, the applicant claimed a process that involved (1) performing a clinical test on individuals and (2) based on the data from that test, determining if an abnormality existed and determining possible causes of any abnormality by using an algorithm. We found that this process was not drawn to patentable subject matter because the essence of the claimed process was the mathematical algorithm, rather than any transformation of the tested individuals. 888 F.2d at 839-41. More specifically, the Grams process was unpatentable because "it was merely an algorithm combined with a data-gathering step," i.e., performing a clinical test. Bilski, 545 F.3d at 963. The claims did not require the performing of clinical tests on individuals that were transformative—and thus rendering the entire process patentable subject matter—because the tests were just to "obtain data." Grams, 888 F.2d at 840. The patent and thus the court focused only on the algorithm rather than the

clinical tests purported to be covered by the claims.

Here, unlike the clinical test recited in Grams, the administering and determining steps in Prometheus's claimed methods are not "merely" data-gathering steps or "insignificant extra-solution activity"; they are part of treatment regimes for various diseases using thiopurine drugs. See Bilski, 545 F.3d at 963 (discussing Grams). As a result, the administering and determining steps are not insignificant extra-solution activity, and the claims are therefore not drawn merely to correlations between metabolite levels and toxicity or efficacy.

3. The presence of a mental step does not detract from patentability

We agree with the district court that the final "wherein" clauses are mental steps and thus not patent-eligible per se. However, although they alone are not patent-eligible, the claims are not simply to the mental steps. A subsequent mental step does not, by itself, negate the transformative nature of prior steps. Thus, when viewed in the proper context, the final step of providing a warning based on the results of the prior steps does not detract from the patentability of Prometheus's claimed methods as a whole. The data that the administering and determining steps provide for use in the mental steps is obtained by steps well within the realm of patentable subject matter. The addition of the mental steps to the claimed methods thus does not remove the prior two steps from that realm.

This analysis is consistent with In re Abele, 684 F.2d 902 (CCPA 1982).[4] In Abele, a method claim called for the

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[4] Although Bilski reiterated that the Freeman-Walter-Abele test is "inadequate" for determining patent-eligibility, Bilski spoke approvingly of the analysis regarding the patent-eligible method in Abele. See Bilski, 545 F.3d at 962-63. Thus, the determination that claim 6 of Abele's patent was patent-eligible subject matter is still good law post-Bilski.

use of X-ray attenuation data, which necessarily involved production, detection, and display with a CAT scan. The method also called for use of an algorithm. We found that the claim was patentable because removal of the algorithm still left all the steps of a CAT scan in the claim; thus, the production and detection could not be considered "mere antecedent steps to obtain values for solving the algorithm. . . . We view the production, detection, and display steps as manifestly statutory subject matter, and are not swayed from this conclusion by the presence of an algorithm in the claimed method." Id. at 908. In the instant case, the presence of the mental steps similarly does not detract from the patentability of the administering and determining steps.

> As we explained in Bilski,
>
> [I]t is inappropriate to determine the patent eligibility of a claim as a whole based on whether selected limitations constitute patent-eligible subject matter. After all, even though a fundamental principle itself is not patent-eligible, processes incorporating a fundamental principle may be patent-eligible. Thus, it is irrelevant that any individual step or limitation of such processes by itself would be unpatentable under § 101.

545 F.3d at 958 (citations omitted). Such is the case here. Although the wherein clauses describe the mental processes used to determine the need to change the dosage levels of the drugs, each asserted claim as a whole is drawn to patentable subject matter. Although a physician is not required to make any upward or downward adjustment in dosage during the "warning" step, the prior steps provide useful information for possible dosage adjustments to the method of treatment using thiopurine drugs for a particular subject. When viewing the treatment methods as a whole, Prometheus has claimed therapeutic methods that determine the optimal dosage level for a course of treatment. In other words, when asked the critical question of "What did the applicant invent?," Grams, 888 F.2d

at 839 (citation omitted), the answer is a series of transformative steps that optimizes efficacy and reduces toxicity of a method of treatment for particular diseases using particular drugs.

Furthermore, the district court erred in finding that the claims wholly preempt use of correlations between metabolite levels and efficacy or toxicity. The court reached this conclusion because "the claims cover the correlations themselves." Invalidity Opinion, 2008 WL 878910, at *11. As discussed above, the claims are to transformative methods of treatment, not correlations. The claims cover a particular application of natural processes to treat various diseases, but transformative steps utilizing natural processes are not unpatentable subject matter. Moreover, the claims do not preempt natural processes; they utilize them in a series of specific steps. See Diehr, 450 U.S. at 187 ("Their process admittedly employs a well-known mathematical equation, but they do not seek to preempt the use of that equation. Rather, they seek only to foreclose from others the use of that equation in conjunction with all of the other steps in their claimed process."). Regardless, because the claims meet the machine-or-transformation test, they do not preempt a fundamental principle. See Bilski, 545 F.3d at 954 (characterizing the machine-or-transformation test as "a definitive test to determine whether a process is tailored narrowly enough to encompass only a particular application of a fundamental principle rather than to pre-empt the principle itself"). The inventive nature of the claimed methods stems not from preemption of all use of these natural processes, but from the application of a natural phenomenon in a series of transformative steps comprising particular methods of treatment. See id. ("[A] claimed process that transforms a particular article to a specified different state or thing by applying a fundamental principle would not pre-empt the use of the principle to transform any other article, to transform the same article but in a manner not covered by the claim, or to do

anything other than transform the specified article."). It is clear that these methods of treatment are § 101 patentable subject matter.

Thus, the claimed methods satisfy all of the requirements under Bilski's transformation prong for patent-eligible subject matter under § 101.

CONCLUSION

For the foregoing reasons, we reverse the judgment of the district court and remand to the court with instructions to deny Mayo's motion for summary judgment that the asserted claims are invalid under § 101.

REVERSED and REMANDED

SUPPLEMENTAL BRIEF

No. 08-1509

Supreme Court, U.S.
FILED
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IN THE

Supreme Court of the United States

CLASSEN IMMUNOTHERAPIES, INC.,

Petitioner,

v.

BIOGEN IDEC, GLAXOSMITHKLINE, AND MERCK & CO., INC.,

Respondents.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

SUPPLEMENTAL BRIEF FOR RESPONDENT MERCK & CO., INC., NOW KNOWN AS MERCK SHARP & DOHME CORP.

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November 9, 2009

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RULE 29.6 STATEMENT

Respondent Merck & Co., Inc., now known as Merck Sharp & Dohme Corp., is a wholly owned subsidiary of (new) Merck & Co., Inc. (formerly Schering-Plough Corporation), which is a publicly held corporation.

Respondent Merck & Co., Inc., now known as Merck Sharp & Dohme Corp., pursuant to Supreme Court Rule 15.8, hereby submits this supplemental brief in response to Petitioner Classen's supplemental brief in support of his petition for a writ of certiorari addressing the recent decision of the Federal Circuit in *Prometheus Laboratories, Inc. v. Mayo Collaborative Services*, 581 F.3d 1336 (2009).

ARGUMENT

Classen argues that the Federal Circuit's ruling against the patentability of his patents below "reached the opposite conclusion on the same set of facts" from its ruling in *Prometheus* and that in so doing, it inconsistently applied its ruling in *In re Bilski*, 545 F.3d 943 (Fed. Cir. 2008), *cert. granted*, 129 S. Ct. 2735 (2009) (No. 08-964). (p. 11). According to Classen, the reasoning of the Federal Circuit in upholding the validity of the Prometheus patents "applies equally to the Classen patent[s], ..." (p. 12).

The underlying premise of Classen's supplemental argument is wrong. His case does not present the same facts as in *Prometheus* because, as set forth in Merck's Brief In Opposition to Classen's Petition for Writ of Certiorari, Classen's patented "invention"—by his own characterization—is merely a mental exercise. Classen's invention is not like the invention of typical immunization or other medical patents, which involve new physical steps or new pharmaceutical agents. Classen's own interpretation of his "invention" as directed to a mental process of thinking about an alleged abstract benefit (decreased risk of later chronic disease) from routine

childhood vaccinations (with no new vaccine, no new schedule and no new physical way of immunizing) is what led both courts below to hold Classen's patents invalid.

Moreover, regardless of *Prometheus* or the outcome in *Bilski*, the judgment below of invalidity of Classen's patents must stand on the alternative ground that Classen did not invent anything new.

CONCLUSION

For the foregoing reasons and the reasons set forth in Merck's Brief in Opposition to Classen's Petition for a Writ of Certiorari, Classen's Petition should be denied.

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